Exhibit G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	:	JOSEPH R. GOODWIN US DISTRICT JUDGE

Myra Byrd, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00748
Angela Coleman, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01267

Dina Destefano-Raston, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01299
Rose Gomez, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00344

Dawna Hankins v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00369
Donna Hankins, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01011

Wilma Johnson v. Ethicon, Inc., et al.
Civil Action No. 2:11-cv-00809
Debra Lynn Joplin v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00787

Margaret Kirkpatrick v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00746
Paula Kriz, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00938

Miranda Patterson v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00481

DEPOSITION OF ELAINE DUNCAN
MARCH 31, 2016

(Caption Continued from Previous Page)

Denise Sacchetti v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01148

Stacy Shultis, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00654
Jennifer Sikes, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00501

Sheri Scholl, et al. v. Ethicon, Inc.
Civil Action No. 2:12-cv-00738
Carrie Smith v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00258

Krystal Teasley, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00500
Lisa Thompson, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01199

Roberta Warmack, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01150

Deposition of
Elaine Duncan
Thursday, March 31, 2016
10:20 a.m.

Reported by:
Barbara J. Carey, RPR

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I N D E X

EXAMINATION:

By Mr. Wallace - Pages 6 and 181
By Ms. Fitzpatrick - Page 120
By Mr. Davis - Pages 177 and 188

EXHIBITS:

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EXHIBITS:

Deposition of Elaine Duncan, taken pursuant to notice, was held at the law offices of Nilan Johnson Lewis, PA, 120 South Sixth Street, Suite 400, Minneapolis, Minnesota 55402, commencing at 10:20 a.m. on the above date, before Barbara J. Carey, Registered Professional Reporter and Notary Public in and for the State of Minnesota.

WHEREUPON, the following proceedings were duly had:

(The oath was administered by the reporter.)

WITNESS RESPONSE: I do.

THE REPORTER: Thank you.

ELAINE DUNCAN,

after having been first duly sworn, was called as a witness and testified as follows:

EXAMINATION

BY MR. WALLACE:

Q. Good morning, Ms. Duncan. We met before; right?

A. Yes.

Q. And I'm going to try to move quickly. I think there was a misunderstanding about the -- the start time, but you're prepared to go forward; right?

A. Certainly.

Q. Okay. I'm going to give you what we're first

going to mark as Exhibit 1.

(Whereupon, Exhibit 1 was marked.)

BY MR. WALLACE:

Q. And I'll represent to you I believe it's a Deposition Notice, and I'm going to ask whether or not you've seen that before, or something like it, asking for you to attend the deposition today and also asking you for some documents.

A. Yes.

Q. Okay. Have you brought any additional documents with you today that you haven't produced in the past?

A. Well, I brought the estimate of the fees for this case, for the WAVE cases, rather.

THE REPORTER: For the what?

THE WITNESS: The WAVE cases, and -- and I have another copy of my CV.

Do you need that?

BY MR. WALLACE:

Q. Is it more up-to-date than what you attached to your report?

A. No, it's the same one.

Q. Then I don't need a copy.

A. All right.

Q. We'll go ahead and mark this as Exhibit 2, then. Can we -- do you mind if we mark this?

A. That's fine.

(Whereupon, Exhibit 2 was marked.)

BY MR. WALLACE:

Q. So in response to the documents that were requested in Exhibit 1, which is the Notice, you brought with you another copy of your CV, as well as Exhibit 2, which is an estimate of hours you submitted in the case?

A. Yes.

MR. DAVIS: Let me just note she does have a number of other notebooks here of all the footnoted documents. Those have all been produced, but just note that she does have them.

BY MR. WALLACE:

Q. So you haven't brought any notes with you that you took in the course of your work?

A. I have not. I didn't have any.

Q. You brought a lot of documents with you that look to be at least eight or nine, if not more, ten binders on the table or benches over there, as well as another four in front of you; is that right?

A. Yes.

Q. And how did you keep track of your thoughts or

ideas or opinions that eventually worked their way into the report?

A. I basically started writing the report with the main document, so I just had the document.

Q. Okay. So if I understand you correctly, what you're saying is that as you came across documents that interested you or that you thought were relevant, you wrote about them in the report?

A. (Witness nodding head.)

Q. And that sort of served as your note-taking, as well?

A. That -- that's pretty much as I did it. So as I would write, I would put the ETH.MESH information next to it, so in the paragraph, and then I transposed those to footnotes.

Q. And with respect to Exhibit 2, the hours, you say it's only an estimate.

Have you not invoiced for your work?

A. I have not invoiced all of the work, just we've sent out an invoice in January, so I added all of these together, and it was only a partial invoice for the TVT-R WAVE. So we're pending an invoice for everything, which we will finish off after this meeting. So that's why this is just an estimate.

Q. Okay. Just to be clear, though, is Exhibit 2 a complete statement of your hours?

A. Complete statement of my hours. What it doesn't include, as I say on this, it doesn't include any expenses, any of our office staff help or the cost of the bindings and that sort of thing.

Q. And the handwriting on the document is yours?

A. That's mine, and I was reminded that I needed to put the hours on there and I hadn't done that, so we back-calculated the hours.

Q. So according to your handwriting on Exhibit 2, you spent 63 hours writing the Prosima and Prolift report that you're here to testify about today?

A. That's correct.

Q. And similarly, you spent about 82 hours working on the TVT-O report?

A. Yes. Yes.

Q. And 52 hours on the TVT-R report?

A. Yes.

Q. And that includes reviewing documents and writing the report?

A. Yes.

Q. It includes editing the report?

A. Yes.

Q. It includes any phone conversations you had with anyone about your report?
A. Anything that went on my fee time sheets, yes.
Q. You, as a result of your work in the case, authored three Rule 26 reports?
A. Yes, sir.
Q. And one of those related to pelvic organ prolapse kits made by Ethicon?
A. The Prosima Prolift, yes.
Q. And the other two related to the TVT-O and the TVT-R; right?
A. Yes, sir.
Q. And you're not offering any opinions on any other products other than those?
A. That's correct.
Q. Okay. We'll mark this as Exhibit 3.
(Whereupon, Exhibit 3 was marked.)
BY MR. WALLACE:
Q. That's your report for the pelvic organ prolapse kit?
A. Yes, sir.
Q. And if you look at the first page, when you discuss the scope of the report, you've identified the exact products on which you're offering opinions; right?

A. In the report, yes, sir.

Q. Okay. If you look at page 8 of the report, I want to just ask you some general questions. You discuss -- and this just generally with respect to the report. You discuss a lot of testing that either Ethicon did or did not do and your reasons for why it was necessary and not necessary; right?

A. Let me just look at that page.

Q. My question has to do with the report generally.

A. That particular page you're speaking of is under the heading of how medical devices are developed today, so this section is not specific to the Ethicon products; this is just a general information outlining my understanding in my practice of how medical devices are developed today. That was the intention of this section.

Q. To back up then, you discussed testing in your report; correct?

A. In a general way.

Q. Well, you actually mentioned specific tests like that would be called for under ISO 10993; right, just as an example?

A. That's an example. I don't think I went into detail of the type of testing.

Q. Okay. In any event, you did discuss testing in your report generally?

A. Yes.

Q. And you talked about different kinds of testing. In fact, you talked about animal testing.

A. Just a minute. I can't recall that was in here.

Q. Look at page 8 under the biocompatibility paragraph.

A. Oh, I said "Testing usually involves sacrificing animals," yes.

Q. And you mean that in the context of developing medical devices?

A. Yes, sir.

Q. And even though you say that the section that you're writing has to do with how medical devices are developed today, your -- that is true, also, in the past; that developing medical devices usually involve some form of animal testing; right?

A. Actually, sir, you're taking that a bit out of context.

May I clarify?

Q. If you feel like you can't answer the question, tell me you can't answer the question.

A. I can't answer the question the way you phrased it because in this section where I'm discussing animal testing, the sentence before it states, "For material that has already been thoroughly tested and/or has a long history of safe clinical use in a predecessor product, little or no further testing is required. Testing usually involves sacrificing animals. Ethical standards caution against unnecessary animal testing."

So the reference to animals in this context is that I'm explaining why we rely on prior history of use for the material in making a biocompatibility risk assessment.

Q. Okay. But that wasn't my question. Perhaps you misunderstood.

All I'm saying and asking you is whether or not, in the development of medical devices, medical device manufacturers typically rely on animal testing --

MR. DAVIS: Object to form.

BY MR. WALLACE:

Q. -- to validate the design of their product?

A. No, sir, I can't say typically.

Q. Sometimes?

A. Sometimes.

Q. Well, in this case, you would agree with me

that Ethicon relied on animal testing to support the use of its PROLENE sutures, which is a predecessor product to the Prolift device?

A. Yes.

Q. And when you make the statement, by the way, about sacrificing animals and that ethical standards caution against animal testing, why are you saying that?

A. It's important to put in perspective the way biocompatibility risk assessment is done. That's what I was, essentially, teaching in this paragraph. I was -- if you read this paragraph, I'm explaining how a biocompatibility risk assessment is -- is done, and following ISO Standard 10993, we take time to understand the prior knowledge about the materials and avoid simply sacrificing animals for the sake of check-boxing that a test was done. If it's already been done, we factor that into the risk assessment.

Q. You would agree with me that, even in your experience and what you've known about medical device makers, that they use animal testing for -- for many other reasons than simply validating a biocompatibility test; right?

A. It varies by the device.

Q. And you're aware of certain studies that were

done on animals with respect to PROLENE?

A. I've read a lot of those reports.

Q. Okay. Are you aware of any -- so I guess what I'm trying to figure out, as you say, ethical standards caution against unnecessary animal testing, are you saying -- I'm just trying to understand.

Are you saying that we shouldn't be sacrificing animals if at all possible? I'm trying to understand the "ethical standards" comment.

A. Well, I certainly didn't say, "If at all possible."

What I'm trying to say is when you read ISO 10993 and take it into the context of today's expectations, here I'm speaking "ethical standards" with a little "S," not standards like 10993, but even --

Q. So what you're saying is a matter of --

MR. DAVIS: She wasn't finished.

BY MR. WALLACE:

Q. Go ahead.

A. So particularly in Europe, the expectation is that we don't run an animal study for the sake of show and tell, to be elaborate. We do it for a specific purpose that offsets the sacrifice of that animal. We give due consideration. For example, there's animal use committees

for every protocol, and when we write those protocols, we have to justify to that animal use committee the value of the study compared to the sacrifice of the animal.

Q. In other words, it's your position that companies like Ethicon are obligated to make animals a priority when they're designing a product?

A. I didn't say a priority, no, sir.

Q. Well, they're supposed to consider the welfare of the animal before they sacrifice the animal?

A. The value that is achieved from the protocol study design, yes. May I give an example?

Q. In other words, we should not necessarily experiment on animals?

A. If I may give an example?

Q. Well, can you answer my question?

A. Well, I think that's generally accepted, that we shouldn't unnecessarily, but if I may explain, it's a part of the protocol and it's a part of the animal use committee assessment. The authors of animal study protocols, today's expectations, are that they provide literature summaries of anything pertinent that's already been done in the past for that protocol, and they have to justify that that study is going to provide information that has not previously been determined. That's more or

less a threshold or ethical use of animals.

Q. But Ethicon didn't give that same consideration to women?

A. Excuse me?

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. Well, where was the -- what did you call it -- the animal use committee, is that what you talked about, you called it; that there are animal use committees? Did I use the right term?

A. That's a general term for it, different -- IACUC is another name for it.

Q. Okay. Where's the women's use committee when we're talking about putting a Prolift device in a woman?

MR. DAVIS: Object to form.

A. Every clinical trial in, as far as I know, most civilized countries in the world, recognize the Helsinki agreement which is the ethical use of experimentation, and all clinical trials have to have informed consent and undergo a protocol review.

BY MR. WALLACE:

Q. And how many clinical trials were done before this -- the products that you've talked about in Exhibit 3 were released to the market?

A. I would have to check my notes. Would you want me to look at that?

Q. Well, you should know that. Don't you know that? Do you know if any were done?

MR. DAVIS: Object to the form.

A. Sir, I have looked at three different types of products. Would you care to say which product you're speaking of?

BY MR. WALLACE:

Q. Any of those that are identified in the -- in the exhibit that's in front of you. Feel free to look at your report.

A. Well, first off, the scope of my report didn't include the review of all of the clinical trials, but I do know that there were clinical evaluation reports conducted on all three of these products, and in those clinical evaluation reports, there are literature summaries and also summaries of experiences for the clinical studies that were conducted, and they're organized and produced in those clinical evaluation or clinical expert reports, as they were called variously.

Q. That's not answering my question. You still haven't pointed me to one clinical trial that was done prior to launch of any of the products.

MR. DAVIS: Object to the form. Asked and answered.

A. I can point you to them if you want me to go to my books and look them up.

BY MR. WALLACE:

Q. So sitting here right now -- you can do that on a break.

Sitting here right now, you don't know, at all, if there were any clinical trials that were done prior to the release of any of the products that are identified in Exhibit 3?

MR. DAVIS: Object to form, and this is not a memory test; she's entitled to refer if she needs to.

A. Sir, I can recall that there were clinical trials, even for the TVT-R and --

BY MR. WALLACE:

Q. We're here -- we're not -- let me just make something really clear. We're here to answer my questions, and we're talking about Exhibit 3. TVT-R is not included in Exhibit 3. We're here to talk about the Prolift and Prosima; okay? Let's look at your report just to orient you because I don't want to confuse you; okay?

You're looking at the Gynemesh PS, Prolift,

Prolift+M and Prosima; okay? You will, later on, be asked questions about the TVT-O and the TVT-R, but not now; okay?

A. Okay.

Q. Just to be clear and so you're not confused, I'm asking you very simply whether or not you know if any clinical trials were done with respect to those products before they were put on the market?

A. My answer is, I would have to consult the notes for these devices because there were various phases of these devices. What I've covered in this report goes back to the PROLENE Soft Mesh, the Gynemesh PS, Prolift, Prolift M and Prosima, and it is my recall that the clinical evaluation reports included listings of clinical data from clinical reports. I cannot recall each one of those.

Q. And you're not sure whether or not they were actually clinical trials; right?

A. Until I check my notes, I would be, you know, concerned that I might be guessing, and I don't want to guess.

Q. Do you believe that the PROLENE Soft Mesh, in and of itself, is one of the kits that you're here to testify about?

A. One of the kits?

Q. (Witness nodding head.)

A. PROLENE Soft Mesh, per se, was not put out as a kit, as far as I recall.

Q. Do you know if the Gynemesh PS is put out as a kit?

A. I would have to check my notes on the Gynemesh PS, but my recall is that that was before the kits, but I'm not certain. I'd have to check. There's a lot of products here.

Q. With respect to the Prolift and the Prolift+M, you would agree with me that those are kits; right?

A. The Prolift, Prolift M and Prosima were what some people refer to as kits because they included instrumentation.

Q. If you look at page 13 and 14 of your report, just going to give you a few examples where it shows up. On page 13 under, "Development of PROLENE Soft Mesh," if you look at the last sentence, it says, "Ethicon's design history file and CE Mark files for PROLENE Soft Mesh are very thorough."

Do you see that statement?

A. Yes.

Q. You make a similar statement right below that

with respect to the Gynemesh PS where you say, "Ethicon's design history file and CE Mark files for Gynemesh PS are very thorough."

Do you see that?

A. Yes.

Q. You say the same thing with respect to the Prolift and the Prolift+M, and I believe you also say that for the Prosima.

What I'm trying to understand is what products are you actually here to testify about?

A. These products that you just listed, as they're written in my report, within -- within the scope of my report, which was the design review, the documentation in the technical files and the quality standards that went into the development of that documentation.

Q. Why did you -- do you know anyone that's bringing a claim in this litigation in WAVE 1 relating to PROLENE Soft Mesh?

A. I don't know anyone. Are you speaking of me personally? I mean, I know the names.

Q. I'm wondering whether or not you were asked to give an opinion on PROLENE soft mesh?

A. Have I been asked to give an opinion of

PROLENE soft mesh? Yes, it's right here.

Q. Who asked you to do that?

A. Butler Snow hired me to do an expert review of the documentation. I'm not sure I understand your question.

MR. DAVIS: Can I say something? It may or may not help. Frankly, she doesn't know which case she's been designated in. My understanding is, if you're worried about whether she's planning to testify in like a Gynemesh PS case, we have not designated her for those cases, no.

THE WITNESS: That's all I know.

MR. WALLACE: I am not here, just so you understand, under the agreement. I'm not here to take a deposition with respect to anybody that's brought a, quote/unquote, a "PROLENE soft mesh claim" or a "Gynemesh PS claim," and I can tell you that you haven't been designated in any Prosima cases.

So I just -- and we can agree to disagree or agree, it doesn't matter to me, Paul, but I'm here to take a deposition today based upon the cases in which you've been designated in the WAVE 1; okay?

And so what I'm asking you is whether or not you know, as you sit here today, whether or not you've

been designated as an expert or asked to, as an expert by Ethicon, to testify in any WAVE 1 cases where the claim is based upon either PROLENE soft mesh, Gynemesh PS or Prosima? Because I don't see any cases in WAVE 1 in which you've been designated in that regard.

MR. DAVIS: She -- I can state she's not going to know which cases she's been designated in, but the record speaks for itself.

BY MR. WALLACE:

Q. Well, and just so we're clear, I'm not here to take a deposition on behalf of clients who aren't bringing those claims. I'm here to take a deposition -- so I don't want this later coming back that because you put in a paragraph at page 13 about the PROLENE soft mesh and discussed it in your report that somehow we're precluded from taking an additional deposition of you. That's my point.

A. Well, if I may, sir, it would seem to me to be self-evident that I was designated as an expert for the scope of the products I have in the report. PROLENE soft mesh is the key implant component for Prolift and Prosima; therefore, I had to evaluate that material in order to produce this report. That's my best answer.

Q. So if I hear you correctly -- and I want to --

and I appreciate you being polite, and I'm going to be polite about it, as well.

What I hear you saying is because you believe that the PROLENE soft mesh is a component or predecessor product in a way that you necessarily had to evaluate it to evaluate the safety of, for example, the Prolift devices?

A. I had to evaluate the documentation for the risk management, for the design control and review, for the general development documentation in the design history file and the technical files, which included the CERs.

MR. DAVIS: Okay. Try to say your "yes" first.

THE WITNESS: Okay.

BY MR. WALLACE:

Q. That's exactly what I was just going to say.

A. Okay.

Q. We don't want to be here all day.

A. Okay.

Q. And I know you don't, either.

A. No.

Q. You want to get home or wherever you're going to go, so if you could just try to answer my question

first. If you really feel an explanation is necessary, I'm going to try to be accommodating to you.

A. Okay.

Q. But not unnecessarily so.

A. Thank you.

Q. Fair enough?

A. Thank you.

Q. Okay. And let's just go back to the statements that I pointed out where you said the design history file and CE Mark files were very thorough.

With respect to all the products -- let's be more specific. With respect to the Prolift and the Prolift+M, did you review the entire design history files for both?

A. I reviewed the documents that I was given, yes, sir.

Q. Okay. But did you review the entire design history file for the Prolift and the Prolift+M?

A. Yes, sir. To the extent I was given the documents, yes, sir.

Q. You don't know whether you were or not?

A. I'm just trying to explain; I had a full download of the documents, and all of the documents were reviewed, yes, sir.

Q. Let's -- let's go at this, maybe, a different way.

With respect to your opinions in this report, is it fair to say that you reviewed enough documents in your mind to satisfy yourself that the company considered the design risk for the products?

A. Yes, sir.

Q. And in fact, that was one of the criteria that you had that you had to satisfy yourself that the company had considered the risk of the Prolift and the Prolift+M and the Prosima; right?

A. Yes, sir.

Q. And the company even had to consider what would be crippling, life-altering risk that might come with the implant of those products; right?

A. I had to review if they had done that, yes, sir.

Q. And you satisfied yourself that the company had, in fact, considered life-altering risks that came with the implant of the product; right?

A. Yes, sir.

Q. And in your opinion, the company considered that, as you say, very thoroughly?

A. Yes, sir.

Q. Let me ask you some basic questions about design in general, and you can tell me whether or not you believe it applies to Ethicon when it made these devices that are at issue in Exhibit 3.

If a company knows that a patient has certain comorbidities that may affect the function of the device, a responsible medical device manufacturer has to consider those comorbidities in its design; right?

MR. DAVIS: Object to the form.

A. Yes, sir, if I may explain.

BY MR. WALLACE:

Q. Go ahead.

A. Often, in the beginning of a design, a company may not know the impact of the comorbidity, so over time, as clinical use expands to different countries or different populations or different users, and more data can be gained, the impact of comorbidities can become more apparent. So during development, sometimes the impact is not known.

Q. Well, based upon the documents that you reviewed and what I'll call good, old-fashioned common sense that I hope we both have, you would agree with me that Ethicon knew that women would have the possibility of multiple vaginal deliveries before they were implanted

with the Prolift device; right?

MR. DAVIS: Object to form.

A. Sir, yes, I understood from the labeling that that was a warning that they had not evaluated that sufficiently.

BY MR. WALLACE:

Q. I'm not asking that. We're going to be here all day. I'm just asking you basic questions.

Did Ethicon know or not know; yes or no?

A. Know what, excuse me? I don't --

Q. That they were going to have -- and I'm trying to use some common sense here so we can get through this.

A. Okay.

Q. They knew -- Ethicon knew that women could possibly have multiple vaginal deliveries before they were implanted with the Prolift or Prolift+M device; right?

A. It is not a yes-or-no answer, sir.

Q. It is a yes-or-no answer.

A. No, sir.

Q. All right. Let's go off the record for a second.

(Discussion held off the record.)

BY MR. WALLACE:

Q. We're back on the record.

Did Ethicon know that women that might receive their product, products that are identified in Exhibit 3, might have had vaginal -- multiple vaginal deliveries before those devices were implanted?

A. I would say yes, they knew they might, which is different from your other question.

Q. Did Ethicon know that some women might -- that might receive this device would be obese?

A. I don't recall seeing any information about obesity, so I can't say if they knew that or not.

Q. You saw no information, at all, in the thousands of documents you allegedly read that discuss Ethicon's state of knowledge with respect to whether or not they knew that women, certain women, could be obese that would receive this product?

A. My answer is no, I do not recall that.

Q. Do you know whether or not Ethicon knew that certain women would have had prior pelvic surgeries or pelvic trauma?

A. Yes, sir, I know that they knew that from my reading, yes, sir.

Q. Did you know that Ethicon knew that certain women, before they received the implant of the device, would have a loss of muscle tone in the area where the

product was going to be implanted?

A. No, sir, I cannot recall if they knew that.

Q. Do you know that the disease itself, pelvic organ prolapse, has, in part, to do with muscle tone?

A. Yes, sir, I know that, but when you asked the previous question about muscle tone, I was not thinking in the general context of muscle tone as much as I was thinking of athleticism. So yes, pelvic floor prolapse is an internal muscle issue, yes. I knew that.

Q. And with respect to all of the things that I just listed; multiple vaginal deliveries, pelvic surgery and pelvic trauma, obesity and loss of muscle tone, would you agree with me that those are commonly described as comorbidities?

A. No, sir, I can't agree with that because I'm not certain in my own mind that they were listed as comorbidities.

Q. Do you agree with me that a company making a pelvic organ prolapse medical device should consider those issues and incorporate them into the design, if possible?

MR. DAVIS: Object to the form.

A. May I correct something I've said previously?

BY MR. WALLACE:

Q. If that answers my question, go ahead.

A. Just give me a second.

The multiple vaginal births, you've mentioned those. When you asked me that question, I was thinking in terms of births after they received the mesh, not before the mesh. So that's what I am trying to clarify in my mind with respect to the question had they, not -- not would they after. When you said it, you said "would they," and I was thinking in terms of that's perfect -- that's a future perfect verb, so I was thinking of in terms of would they have those births after they got the mesh.

Now that you put it in the context of the comorbidity question, I understand you were asking would those women have had, previous to their surgery, multiple vaginal births, and now I understand your question.

Q. Okay. And just to be clear, I said earlier, prior to the implant. So all of these things, like prior pelvic surgery --

A. The first time you asked it --

Q. Let me finish my -- we're going to step all over each other's toes if you keep doing that.

A. Sorry.

Q. My point is, all of these things, women were going to go -- did Ethicon know that women were going to

be obese, have prior pelvic surgeries and multiple vaginal deliveries and prior pelvic trauma prior to the implant? That's what I was getting at.

Now, with that in mind, do you agree with me that a responsible device manufacturer should take those prior conditions or events into account when designing the product?

A. Yes.

Q. What documents, when you say that their design was thorough, what documents or evidence do you have to show me that Ethicon considered those events or issues that I've just described?

A. I brought these along. Would you like for me to --

Q. If you need to consult them, go ahead.

A. Okay. Just a minute.

Q. I'm sorry, go ahead.

MR. DAVIS: She wants me to pull up the complete document.

A. Because of their size, we didn't print the full documents for both of these, but this is my footnote for the Prolift and for the technical documentation -- design development, I should say, documentation, and then this is the technical file document.

BY MR. WALLACE:

Q. And you think that, with respect to the Prolift file, that the documents you're showing me would demonstrate that Ethicon considered the multiple vaginal deliveries, the prior pelvic surgery, the pelvic trauma in its design and addressed it if at all possible?

A. If it -- if the documents aren't specifically in this document, they're referenced by this document.

Q. Okay. And why don't we, to be safe, I'm going to give the court reporter the Bates Number and I'm going to ask her to mark those.

So the first document that you've given me is called "Gynecare Product Description Document." It says page 1 of 11, although I only have one page, and it's ETH-03261; right?

MR. DAVIS: Can I see that?

BY MR. WALLACE:

Q. And the second page that you've given is the "Gynecare Prolift Pelvic Floor Repair Systems CE Mark Technical File" dated September 21, 2008, ETH.MESH.06402274; correct?

A. Yes.

MR. DAVIS: But Ed, let me correct one thing. You said that -- I think you said this document is

11 pages. The document on my computer is 4,169 pages.

MR. WALLACE: All I'm saying is on the right-hand column of the document, it says page 1 of 11. I'm not representing to you something that I can't see. I'm identifying the document for the record.

THE WITNESS: Okay. So that's not the full size of the document.

BY MR. WALLACE:

Q. So you're pointing me to the Prolift technical file; right?

A. The second one is the Prolift technical file.

Q. And what else are you pointing to me that's 4,000 pages long?

A. Actually, you'll see if you look at that first page --

Q. Let me ask the question.

A. Yes.

MR. DAVIS: She said it was Footnote 21, I think.

MR. WALLACE: Okay.

A. Yes, and this number, right there at the bottom, the ETH number, in my footnote is 950, not 951, and so the first page was not printed, and that's probably why you're not seeing the full size of the document.

BY MR. WALLACE:

Q. In the interest of not belaboring the point, the bottom line is you're telling me that in Footnote 21 in the document of which you don't have a full copy of, Footnote 21, Ethicon considered the -- Ethicon considered the issues that I raised earlier, which included multiple vaginal deliveries, prior pelvic surgery and the like; correct?

A. That one, plus the other one that you -- this one plus this is the technical file on the same topic, and this is --

Q. Can we mark this?

A. Uh-huh (affirmative).

(Whereupon, Exhibit 4 was marked.)

THE WITNESS: It's actually Footnote 22 because this one was with the Prolift M.

MR. WALLACE: Can you mark that one, as well?

(Whereupon, Exhibit 5 was marked.)

BY MR. WALLACE:

Q. Can I dumb this down for me?

What you're telling me is that in Footnote 22 --

A. 21 and 22.

Q. -- Footnote 21 and 22, Ethicon considered the issues that the women had prior to the implant; correct?

A. As I said previously, yes, they are in this document or referenced by this document. They may not be included in this document per se, but in this document, they have referenced it.

Q. Okay. In other words, even though they only may be referencing the issue, in fact, you believe that Ethicon considered those issues and incorporated them into the design-planning process of the Prolift, Prolift+M and Prosima; right?

A. Yes, sir, I do.

Q. Thank you. And for example -- let me just move on.

If you're implanting a medical device in a space that needs to be elastic, like the vaginal space, you want to figure that out in the design phase; right?

A. Elastic? Can you elaborate? I didn't understand.

Q. Expand. You would agree with me that the vaginal space is a dynamic space that is not static; in fact, it expands and contracts?

A. Sir, I can't agree with you. I don't have expertise in that area.

Q. Okay. Let's assume that I'm correct then. You're an expert designated to testify, so I'm going to use a hypothetical with you; okay?

Let's assume that I'm correct -- let me back up for a second.

You don't know whether or not the vaginal space expands and contracts?

A. No, sir, I was not saying that. I was saying no to your previous question.

Q. Okay. Let me ask you this.

Do you know whether or not the vaginal space expands and contracts?

A. Yes, sir.

Q. And you would agree with me that that would include the area in which these devices are implanted?

A. I cannot answer that question because it's -- there's a premise there that I would disagree with.

Q. Tell me what you disagree with.

A. I don't believe these materials are implanted in the vaginal space. It's not inside the vagina.

Q. Do you believe that they're implanted in an area that requires elasticity?

A. I do not know that.

Q. Okay. Have you reviewed the instructions for

use in this case?

A. Yes, I have.

Q. And you would agree with me, then, that it talks about bidirectional elasticity as one of the benefits of the devices; correct?

A. As -- excuse me for -- I'm trying to say yes or no, but I can't, because my understanding, again, is that that doesn't require the mesh to be elastic; it's part of the surgical procedure that allows the material to be elastic.

Oh, were you speaking of Prolift M? You got that file out just now. See, your -- you confused me with these questions because you're not specific to the products.

Q. There's three products at issue; the Prolift, the Prolift M and Prosima.

A. Yes, and they're not the same type of materials, so you have to be specific, please, when you ask me a question.

Which one are we speaking of?

Q. I'll be as specific as I need to be.

A. All right.

Q. And if you're confused by the question, I'd like you to tell me that you are.

A. I did.

Q. So you, regardless of whether it's the Prolift, the Prolift+M or the Prosima, do you believe that Ethicon thought the elasticity of those devices was important to their function?

MR. DAVIS: Object to the form.

A. Sir, I cannot answer that question.

BY MR. WALLACE:

Q. Why not?

A. Because I do not know what they believed at the time.

Q. Well, you've reviewed documents that speak to elasticity; right?

A. Yes, with respect to the Prolift M, that material changed its properties over time.

Q. Well --

A. Is that what you mean by elastic? Could you show me in the labeling what you're talking about because I don't know. Elastic means a lot of things to different people. What specific things are you speaking of?

Q. Do you believe that any of these -- the three devices that we're talking about -- the Prolift, the Prolift+M or the Prosima -- needed to be flexible at all in the human body?

A. Yes, sir, now you've used the word "flexible," and "elastic" and "flexible" are different for me.

Q. Can you just answer my question?

A. Sir, I just said yes.

Q. My name is Ed. You don't need to call me "sir." I appreciate the courtesy, but the bottom line is -- let me just ask the question and you answer, okay, as you need to. Let's stay on the question that I asked.

Do you believe that Ethicon thought it important that the Prolift, the Prolift+M and the Prosima be flexible inside the human body; yes or no?

A. Flexible during delivery and placement, yes.

Q. What about afterwards?

A. The mesh is ingrown and will not remain flexible, so they would not have believed it should stay flexible or elastic over time, but it needs to be that for presentation.

Q. In other words, you believe that once the tissue ingrowth occurred, there was no more reason for the mesh to be flexible according to Ethicon; right?

A. Sir, when you added "according to Ethicon," I cannot recall specifically how they expressed it, but it is my understanding that when the mesh is ingrown, the physical properties change and flexibility is no longer an

attribute of concern.

Q. And it's your understanding that if the mesh is stiff after ingrowth, it is not a concern; right?

A. I would say I don't know how to answer your question. They attempted to design Prolift M as an alternative, and I do not have knowledge to tell you from a biomaterials point of view if that was successful. It's not my expertise.

Q. Do you think that you have an obligation as an expert that is testifying in this case to have an understanding of what design attributes Ethicon thought were relevant?

A. Yes, sir, I can tell you that looking at the reports, if you would like for me to go back to those reports. We're talking about three different products here, and so if you want to speak to each one of those, I will try to answer each one of them. They had different attributes, particularly Prolift M, that they were trying to design for. Prolift M had a portion that was absorbable, which changed its properties after implantation. So when you try to put all three of these products together, I have a hard time trying to answer one question yes or no.

MR. WALLACE: Let's go off for two

minutes.

(Whereupon, a recess was taken from 11:13 a.m. to 11:19 a.m.)

BY MR. WALLACE:

Q. You want to clarify an answer?

A. Yes.

Q. Go ahead.

A. Previously we were talking about "elastic" versus "flexible," two different words. In the development of the Soft PROLENE Mesh, the team sought for Soft PROLENE Mesh, for it to be more flexible than the prior PROLENE mesh, and that was -- so yes is the answer to the "flexible" question.

Also, then, these two footnotes, I already gave you 22, but additional Footnote 23 covers the Prolift M development, which was the portion that is absorbable, that changes its properties after implant; okay? That's what I was trying to clarify.

Q. Thank you for clarifying that, and if I understand you correctly, you've now pointed to Footnotes 21, 22 and 23 --

A. Yes, sir.

Q. -- as the evidence that you looked at and reviewed and concluded that Ethicon considered the issues

that women had prior to implant, which included, for example, prior vaginal deliveries, prior pelvic surgery and the like; correct?

A. That's correct.

Q. Okay. And it would be that -- and I would assume that it would be the same thing for a hysterectomy; that you would point to the same footnotes that Ethicon considered that some of the women that would be receiving this device would be -- either have had a hysterectomy or would be concurrently receiving a hysterectomy with the implant of the device?

A. I believe that was considered, yes.

Q. And it was considered in the design, and you would point me to your report and, more specifically, you believe, as you sit here today, that it's included in those three footnotes?

A. But it was also included in CER reports and -- that came subsequent, and I believe this particular reference is an early technical file, Number 22.

Q. And you've pointed out correctly that the Prosima+M (sic) has a partially absorbable mesh?

A. Yes, sir.

Q. So you would agree with me the three devices -- the Prolift, the Prolift+M and the Prosima --

are all different devices?

A. No, sir, they're not altogether totally different.

Q. I didn't say altogether totally different. They may share some similarities; correct?

A. They share similarities.

Q. They all are designed to treat pelvic organ prolapse?

A. Yes, sir.

Q. But at the end of the day, they were all cleared as different products?

A. They were cleared separately, yes.

Q. Okay. And you would agree with me that they're different devices?

A. They're different kits.

Q. And they're -- they use different materials, for example?

A. Well, the Prolift M is different, but the other -- others are the same.

Q. You believe that the Prosima is identical to the Prolift?

A. The mesh is identical with the exception of the manufacturing modifications.

Q. Do you believe -- you would agree with me that

those three devices present different risk?

A. I would agree that they present different risks from the different surgeries, yes.

Q. And you would agree with me that they are different in the sense that their properties change over time?

A. I have difficulty with the underlying premise of that question. I can't answer it.

Q. Let me ask it a different way.

The Prolift+M is different materially from the Prolift; correct?

A. It has a -- a single different material added.

Q. And you would agree with me that, because of that, the varying properties change differently over time between the Prolift+M and the Prolift?

A. Could you rephrase that? I'm sorry, I couldn't hear you.

MR. WALLACE: Could you read it back, please?

(The record was read back.)

A. Prolift+M varies from the others, yes.

BY MR. WALLACE:

Q. Okay. The -- let's move on.

You would agree with me that the instructions

for use is designed to communicate with an implanting physician; right?

A. Yes, sir.

Q. And one of the things that the IFU is designed to do is to make physicians aware of certain complications that might come with the implant of the device, whether through surgery or long-term; right?

A. Yes, sir.

Q. So the company uses the instructions for use to warn of risk?

A. That's one.

Q. And you would agree with me that if Ethicon, for example, knew about certain risks that came with the device before launch, that -- that they should put it on the instructions for use?

MR. DAVIS: Object to the form.

A. If they knew -- I'm just rephrasing that question.

If they knew in advance of certain risks, they should put it on the instructions, yes.

BY MR. WALLACE:

Q. Okay. And you would agree with me that they should do that before the product is released to the market if they hadn't -- (inaudible); right?

A. You dropped your voice. I couldn't -- can you --

Q. I'll speak up for you. Why don't I withdraw the question. I'll ask it again.

A. Okay.

Q. Actually, let's do something different. Why don't you take a peek at this next exhibit?

(Whereupon, Exhibit 6 was marked.)

BY MR. WALLACE:

Q. You've seen Exhibit 6 before; right?

A. It's familiar, but I need to refresh on it. Is that all right?

Q. Go ahead.

MR. DAVIS: You don't have an extra copy; do you?

MR. WALLACE: I thought I gave you one (handing).

MR. DAVIS: Thanks.

BY MR. WALLACE:

Q. I have some very specific questions about that document, Ms. Duncan.

A. Okay.

Q. One is, you've seen this before?

A. Yes.

Q. And you would agree with me that it is an early design concept document that was created by Ethicon with respect to its -- what became its Prolift devices; right?

A. Yes.

Q. And would you agree with me that it discusses -- it discusses some of the concepts and ideas that the company had about these devices?

A. It appears so, yes, sir.

Q. And this is a -- a document that's commonly prepared at the beginning of the design of the document; right?

A. It is, yes.

Q. And it lays out the company's vision for what it wants to achieve and the market that it wants to address; right?

MR. DAVIS: Object to the form.

A. At an early feasibility level; correct.

BY MR. WALLACE:

Q. So in other words, it might look at what it believes the unmet needs are in the market; right?

A. Typically. I don't -- I haven't had a chance to confirm that this does, yes, but go ahead.

Q. You would agree with me that it can,

oftentimes, in the concept phase, which is addressed in Exhibit 6 also address an early idea what the financial commitment of the company might be to the project?

A. Often at this level, yes.

Q. All right. And you would agree with me that you do see that Ethicon in that document, Exhibit 6, discussed what it believed were the unmet needs in the market?

A. Yes, sir, it does.

Q. And it has some early design drawings; right?

A. Yes.

Q. And you would agree with me that the document is dated June 27, 2003, which is before the launch of the devices, the Prolift devices that we're talking about today; right?

A. Sir, I don't recall the date of the launch. I'll take your word for it.

Q. Look at page 6 of the document, the unmet needs.

A. Yes, sir, I'm looking at that.

Q. And you'll see that the company expressed an unmet need that they wanted to come up with a standardized procedure which had a consistently low complication rate.

A. Yes, sir.

Q. Do you see that?
A. Yes.
Q. And you would agree with me that that was a goal of the company; right?
A. Yes, sir.
Q. Would you please look at page 9? You'll see a diagram on page 9, which talks about the concept progression.
Do you see that?
A. Yes.
Q. And you would agree with me that that generally describes how Ethicon was going to come up with the concept; in other words, they were going to work with key opinion leaders in France to come up with the feasibility of the Prolift, which would ultimately result in the design of the product?
A. That's my recall, as well, from reading, yes.
Q. And you actually have seen other documents that tell that story; right?
A. Yes, sir.
Q. If you look at page 16, it describes the anterior TVM procedure.
A. 16?
Q. 16, please. And at the bottom, it talks about

some of the advantages that the company would like to have with the anterior TVM procedure.

Do you see that?

A. Yes.

Q. And just to take a step back for a moment to orient ourselves with respect to the Prolift device, there's the anterior, posterior and total Prolift devices; right?

A. Yes.

Q. And you know by looking at this document that the company was considering, already, the anterior in 2003, and that's what this page 16 we're looking at?

A. That's what we're looking at, yes, sir.

Q. So we are on the same page?

A. Yes, sir.

Q. And one of the things they wanted with the anterior was to promote a consistent repair and reduce operative time; correct?

A. Yes.

Q. That was a goal of the company?

A. It says the advantages of this approach would be to do that.

Q. In other words, if the anterior was developed, that's an advantage that they wanted the anterior Prolift

to have; correct?

A. That would be an advantage if they followed this path, yes.

Q. Look at page 31 which lists manpower.

Do you know, by looking at page 31 and also all the thousands of pages of documents that you've looked at, that Scott Ciarrocca was the project leader for the Prolift device?

Do you see his name there?

A. Yes.

Q. And it's common in the concept design phase to list who might be on the team that's ultimately going to develop this device in the company; right?

A. I believe, sir, this is referring only to the feasibility phase.

Q. Correct. But you would also agree with me that Scott Ciarrocca became the project leader for the Prolift; right?

A. I recall that from my reading.

Q. If you look at the next page, the concept that Ethicon expressed in 2003 was that this product would be, from the feasibility stage to the product launch phase, take about one year?

A. Yes.

Q. And in order to come up with the idea that this was going to be launched in one year, the company had to make certain assumptions about the project; right?

A. That's typical. I don't know what their assumptions were off the top of my head, yes.

Q. Well, why don't -- you've actually, fortuitously, flipped right to the page I was going to direct you to.

A. Okay. Thank you.

Q. Page 34.

A. Okay.

Q. You would agree with me that the company listed, on page 34 of Exhibit 6, its critical assumptions about the project; right?

A. Yes.

Q. And the top two were that, one, the device was going to be cleared through the 510(k) system; right?

A. Yes.

Q. And that ultimately happened?

A. Yes.

Q. And that the devices would be CE marked at initial offering, and that actually happened?

A. It's my recall, yes.

Q. And the third thing is that there would be

clinical trial of implants with six-month follow-up would be sufficient to support a launch; correct?

A. That's what they have here, yes.

Q. Okay. Do you know, as you sit here today, whether or not that actually happened?

A. I'm going to try to recall, but I would like the opportunity to check my notes on this. It's my recall that -- you see, we've got three different products here, so my recall, that one of these did not go through a conventional clinical trial but relied on the clinical history from the French physicians. That's my recall.

Q. And the assumptions that were being made were about the project and how this was going to hit the market; right?

A. This is the assumptions in that plan, yes.

Q. And if you look at the next page, the critical assumptions that were being made were about the performance of the product itself. In fact, it says that at the top of the page; right?

A. Yes.

Q. And so that's what the company was considering were critical about how the product was going to perform?

A. Right.

Q. And there are six bullet points that the

company considered critical about the products' performance; right?

A. It's -- it's what it says here, yes.

Q. And looking at the bullet point, it says, "Creates no additional problems possible with needle passage through obturator foramen."

A. "That's what it says, yes.

Q. In other words, the company found it critical with respect to the product that there would be no additional problems possible with needle -- needle passage through that space?

A. Yes, sir.

Q. The transobturator space?

A. Yes.

Q. And you believe that the company considered and addressed that critical assumption; right?

A. Yes. Yes.

Q. And that's your opinion that you're stating as an expert in this case?

A. I believe they did, yes.

Q. And the next bullet point says, "Creates no additional complications (erosion, pain)."

Do you see that?

A. Yes.

Q. And you would agree with me that it's your expert opinion that the company, in fact, assumed that as a critical assumption about their products at issue in Exhibit 6, and that it's your expert opinion in these cases that, in fact, Ethicon considered them and that the products, themselves, created no additional complications; correct?

A. Yes, I -- with the caveat that, as I understand this statement, their meaning creates no additional complications like the other complications that have already been identified, not -- not that they're saying you can't have erosion or pain; they're speaking of no additional complications beyond the known complications. That's my interpretation of that bullet. I just want to clarify that.

Q. Let's look at page 37, which is a risk assessment.

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. It says "Risk Assessment" at the top of the page; correct?

A. It says it, but -- yes.

Q. And you would -- we would agree that this is not a full-blown risk analysis that the company conducted

on page 37, but rather, it captures what the company felt important, the project team at that time felt important about the concept of this device as it related to risk; right?

A. I would agree it's a summary.

Q. And it's an early assessment?

A. Yes, sir.

Q. And it's what they're identifying as important early on in summarizing that; right?

A. Yes.

Q. And you know that, at this time, they were working with these French physicians and, in fact, one of the risks that they point out on page 37 is that the work by this French group, that one of the risks is that the product that they're coming up with may not be a less traumatic transvaginal approach to pelvic floor repair; right?

A. No, sir. I don't follow your -- your conclusion from that. Can you --

Q. Well, what do you think you're seeing?

A. What line are you looking at?

Q. Looking at the first box under "Risk."

A. Yes.

Q. It says, "Kit and procedure as outlined by

French group TVM does not address the need for a standardized product for less traumatic, transvaginal approach to pelvic floor repair."

Do you see that?

A. Oh, I understand now, yes.

Q. Okay. So you agree with me that one of the risks was that the French group's product would actually be more traumatic?

MR. DAVIS: Object to the form.

A. That's not the way I interpret it.

BY MR. WALLACE:

Q. How do you interpret it?

A. I interpret it as it would not meet that need. This risk assessment is also in the context of success of the project, so what they're saying is the risk is what they are proposing does not address the need, not that it would be more traumatic. It says it doesn't address the need, and in that circumstance, the impact on the project would be that you would go back to the concept stage or you would have a delayed launch. This is not a risk assessment from a patient point of view; this is a risk assessment from a project point of view.

Q. In other words, that the project may not do what it's supposed to do?

A. The impact on the project would be that it might have to go back to the concept stage or they may have to have more resources, they would delay the launch, or they could re-evaluate the project altogether. That's -- that's what this risk assessment is describing.

Q. And one that does actually address the patient is that there would be erosion and recurrences due to mesh used and if, in fact, that became a problem, they would try to mitigate that by monitoring the patients in the studies; right?

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. Do you see that?

A. It's a mitigation strategy for the project, yes.

Q. And that if -- and its potential impact, if that was the case, they would need to go back in the concept stage, delay launch and increase resources; right?

A. Yes, sir. That's what it says.

Q. And the final thing that I'll point you to on that page, it says one of the risks is that their approach creates an additional risk by the obturator passage.

Do you see that?

A. That's the risk that they're identifying, yes,

but the design could do that, yes.

Q. And that if there was additional risk that was presented that, in fact, the company would have to -- need to go back into the concept stage, delay launch and increase the resources; right?

A. That's possible, yes.

Q. And we know that by looking at that, but we also know that, by looking at what I showed you earlier on page 35, where one of their critical assumptions was that they wanted to create no additional problems with the transobturator approach; right?

A. That's correct.

Q. And we know that --

A. But may I correct you just a moment -- or not correct you, but correct my statement, excuse me?

I also see that they had identified needle passage as an existing risk, that that has always been for all of these products that's been a known risk, but this specific design is what they're speaking of here.

Q. In other words, that the specific design at issue created no additional risk?

A. That's right.

Q. So in other words, if a product had poorer outcomes --

A. Yes.

Q. -- with respect to the use of the transobturator space, that that would be something that is an additional risk that would require the company to go back to the concept stage and delay launch; correct?

A. I believe that's true, which is why they worked hard on that aspect, yes.

Q. Right. And in your words, they did a very thorough job assessing those additional risks?

A. I believe they did, yes.

Q. And as part of that -- and I don't want to spend too much time on you and I trying to figure out how these products work, but wouldn't you agree that the total Prolift kit uses six arms of mesh that are anchored?

A. That's my understanding, yes.

Q. Okay. And the posterior uses four; right?

A. Yes, sir.

Q. And the anterior uses two arms as anchors?

A. Yes.

Q. And if we needed to, we could look at pictures, but you generally agree with me; right?

A. I'm good with that, yes.

Q. And that these arms and the passages were in the obturator space; correct?

A. Yes.

Q. And the design of these arms was to anchor themselves through tissue ingrowth in those spaces?

A. Yes, sir.

Q. Speaking of Scott Ciarrocca -- I pronounced that correct; didn't I?

A. I wouldn't know; I've not heard it pronounced.

Q. He was one of the employees of Ethicon that worked on the failure modes and effects analysis that were done with respect to the three products that we've been talking about?

A. It's my recall, yes.

Q. And in other words, Scott and his team -- it wasn't him alone -- prepared paperwork relating to how the instruments might be used or misused; right?

A. Yes.

Q. Okay. And they looked at potential ways that the safety of the patient may be affected?

A. It's my recall.

Q. And they tried to document the ways in which patient safety may be impacted by the implant of these products in the Prolift and the Prolift+M; correct?

A. They were done in different phases on different documents.

Q. Was it -- was their work done just to get the product cleared, or were they actually concerning themselves with the safety of the device, as well?

A. Sir, it's my recall that these -- the team was very focused on the instrumentation because the material had already been established in this clinical indication. The -- the Prolift and then, later, the Prosima, were focused to the delivery system for the existing Soft Mesh. That's my interpretation of the projects, as I read them.

Q. Okay. But I just asked whether or not they wanted to get the product cleared or whether or not the project team for the Prolift, for example, was concerned with safety.

A. I believe they were concerned with the safety, which is why they were developing the instrumentation, yes.

Q. And so, with respect to the instrumentation, you're talking about the trocars themselves?

A. Yes, and the delivery procedure. The instruments would have to have a surgical procedure described with them, and they did it at work with the physicians.

Q. And you would agree with me, as a biomedical engineer, that when you're describing the procedure and

the way it's done and invented by the company, that that's actually part of the product's design itself; right?

A. Agreed.

Q. And what you're saying is the company had an obligation to satisfy itself that its delivery system, which was part of the design of the product, had to be safe?

A. Yes, sir.

Q. Do you agree with me that the company had an obligation to look at whether or not the implementation of additional mesh by using the Prolift device would equal more safety complications for the patient?

A. I have to have you repeat that.

Q. Let me ask it more simply.

Do you believe that the company had an obligation to look at the amount of mesh that it was putting in women and determine whether or not putting more mesh in a woman would potentially create more risk?

MR. DAVIS: Object to the form.

A. My answer is no, and the reason is because it's my understanding that the procedure kit did not, in and of itself, add more mesh because the amount of mesh for each of these procedures was already established by the physicians who were putting the mesh in without the

kits, that the amount of mesh had already become an understood requirement because the Soft Mesh was already used in this indication for use prior to the creation of the kits.

So that's why I have to say no; because I'm saying I don't believe that they were increasing, as you've put it, the amount of mesh. The amount of mesh was already established by the procedure created by the physicians before the kit ever came along. That's my understanding of the development project.

BY MR. WALLACE:

Q. And you believe that based upon Ethicon documents that you've seen?

A. That was the end of your question?

Q. (Nodding head.)

A. Yes.

Q. So in other words, what you're saying is Ethicon didn't have to assess the risk of the amount of mesh it was putting inside of women because a similar amount of mesh was already being used by physicians anyways?

A. Yes, sir, because you said "more," so I don't believe there was more created by Prolift or Prosima.

Q. Do you think that the mesh was being put in a

different area and the company had an obligation to assess how that amount of mesh in a different area would affect the safety of the patient?

A. The mesh was already cleared for that indicated use. The kit came along to establish a standardized procedure, but the mesh was already cleared, both in the CE in Europe and in the U.S. for that indicated use.

Q. What indicated use?

A. Pelvic floor repair.

Q. Okay. You realize that the Prolift device was, for the first time for pelvic organ prolapse, being put in an entirely new area called the transobturator space, the obturator foramen?

A. Yes, sir, but not --

Q. The company itself --

A. Wait, wait, wait. No.

MR. DAVIS: Let her finish her answer.

A. Excuse me, the kit enabled that, but it had already been done.

BY MR. WALLACE:

Q. Sure of that?

A. I would have to confirm that with my notes, but I -- my -- my footnotes, but I believe that that had

already been described in the literature. That was a part of their review.

Q. You would agree with me that the document that we just looked at assessed additional risk in the transobturator space. That's one of the things that the company wanted to address; correct -- right there (pointing)?

A. Yes.

Q. One of the ways in which to seek feedback on how a product might be performing early on is to just seek out physicians' opinions on it; right?

A. You dropped your voice again, sorry.

Q. One of the things that the company might be able to do and, in fact, did do, was seek out the opinion on physicians on how their product was performing?

A. Yes, sir.

Q. And you would agree with me that you've seen documents where French physicians that had this product before it was released to sale in the United States expressed their opinions about how the product was performing; right?

A. They have, yes.

Q. And you would agree with me that this was a novel product; right?

A. A what?
Q. That this was a novel product?
MR. DAVIS: Object to the form.
A. The instrumentation kit was new, but the surgery was not new.
BY MR. WALLACE:
Q. Was the design of the mesh new?
A. There were new attributes to make it work with the kit, yes, sir.
Q. Like what?
A. Folding and attachments.
Q. More arms?
A. More arms. It was pre-cut because, prior to the kit, the mesh was not pre-cut, is my recall.
Q. In other words, the -- while you believe that the mesh properties were made of the PROLENE --
A. Soft Mesh.
Q. -- Soft Mesh, that, in fact, you would agree with me that the design of the Prolift mesh, itself, in terms of its shape and size was new?
A. It was pre-shaped and sized in the kit, yes, sir.
Q. Was it new --
A. I --

Q. -- or not? I mean -- get an answer to my questions.

A. The material had not been sold previously pre-cut and set up for the kit; it had been sold as a flat sheet and altered by the physicians.

Q. If Ethicon called this a novel product, would Ethicon be wrong?

A. Sir, I am a regulatory person, so I look at similarities and differences, and if the marketing people decide to call it novel, that's another interpretation. I couldn't speak to that.

Q. So you can't answer the question?

A. I can't answer the question.

(Whereupon, Exhibit 7 was marked.)

BY MR. WALLACE:

Q. You'll see Scott Ciarrocca's name at the top of Exhibit 7?

A. Yes.

Q. And this is dated July 21, 2003.

Have you seen that?

A. Yes.

Q. And if you look at the prior exhibit, Exhibit 6, it's dated June 27, 2000 --

A. Yes.

Q. And you would agree with me that, at the bottom of the first page, Scott is asking Professor Jacquetin and Dr. Cosson questions about how this device would perform; correct?

A. Let me read it a moment, if you would please. He's asking about slippage.

Q. And Dr. Cosson responds; right? And he gives his opinion about the product. At least in part, he notes that the problems are more erosion and retraction and that it's possible to have a recurrence but it is usually due to a retraction of the mesh and the arms of the mesh.

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. Do you see that?

A. I believe, in the context, he's speaking without the instrumentation. He's saying this is an issue we have to address.

Q. And he's saying that there's problems with more erosion and retraction; correct?

MR. DAVIS: Object to the form.

A. If there's slippage of the implant, the problems are more erosion and retraction.

BY MR. WALLACE:

Q. Have you read any of the testimony relating to

this document?

A. I don't believe I have.

Q. Yet, you still gave the opinion that Ethicon was very thorough and considered all of the risk in designing its document -- or its devices; correct?

A. I believe they considered this risk, yes.

Q. But you haven't read any of the testimony relating to this document?

A. I read a lot of different testimony. I can't recall if I read this or not. I've seen the e-mail, but I can't recall if I read his -- I don't believe I've read his testimony.

Q. And if Ethicon did not address the concerns that were being raised by the French physicians, did it meet or exceed all applicable industry standards, as your opinion states?

MR. DAVIS: Object to the form.

A. There's a presumption there. I can't answer the question as asked because you're saying they didn't. I don't understand that they didn't.

BY MR. WALLACE:

Q. Well, let's assume that they didn't. Let's assume that there were concerns about more retraction and erosion prior to the product being launched that were

raised to Ethicon and Ethicon had knowledge of that.

A. You're not speaking of this e-mail anymore, because I don't believe that's what he's trying to say here.

Q. Can you do me a favor? Can you not interrupt my questions?

A. Sorry.

Q. Let me ask the question.

A. Sorry.

Q. I'm going to go back. You can put that down.

A. All right.

Q. Maybe that will help.

If Ethicon had knowledge that there were problems with more erosion and contraction that presented different risks with respect to these devices before these devices were launched, would Ethicon be failing to meet the standards that applied to them as a reasonable manufacturer of medical devices?

MR. DAVIS: Object to the form.

A. You're speaking hypothetically?

BY MR. WALLACE:

Q. Yes.

A. Yes, hypothetically, yes. I don't believe they had the knowledge you're speaking of.

Q. Well, if they --

A. Because you said "more." I don't believe that they had more -- that there were more erosions and that they had prior knowledge of more erosions before they put the product out.

Q. Let's just talk about risk generally.

Would you agree with me that if they had knowledge that the Prolift device presented risk of traumatic injury to the patient that were not identified in the instructions for use and they failed to put that information on the instructions for use that they failed to meet the standards of a reasonable device manufacturer?

MR. DAVIS: Object to the form.

A. All of those "ifs" -- all of those "ifs" would have to be correct, and then I would say yes.

BY MR. WALLACE:

Q. You would agree with me if all of those "ifs" were true?

A. If all of those "ifs" were true.

Q. But you don't believe, based upon your review of documents in this case that, in fact, the hypothetical that I gave you is true?

A. I don't believe that it is true.

Q. You have a right to say that. I said you have

a right to say that. That's fine.

MR. DAVIS: Let's get to a point where we can take a short break to stretch my legs.

MR. WALLACE: Give me a few minutes.

(Whereupon, Exhibit 8 was marked.)

BY MR. WALLACE:

Q. Have you seen this document before?

A. It's familiar.

Q. Why don't you look. It's a two-page document; correct?

A. Yes.

Q. And it's an e-mail from Axel Arnaud to others; right?

A. Yes.

Q. And at the bottom, in 2005, he is saying that he wants to add a warning to the -- to the instructions for use; correct?

A. Let me finish.

Q. Okay.

A. Okay. I've read it.

Q. Okay. Thank you.

If you go to the second page, you'll see that Axel Arnaud is saying that he wants to add an additional warning to the instructions for use, and I'll state what

it says. In capital letters, it says, "WARNING."

Do you see that?

A. Yes, sir.

Q. It then goes on to say, "Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/and commonly lead to complications such as vaginal erosion and retraction, which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse."

Do you see that?

A. Yes.

Q. He goes on to say, "Clinical data suggests that the risk of such a complication is increased in the case of associated hysterectomy. This must be taken into consideration when the procedure is planned in a sexually active woman."

Do you see that?

A. Yes.

Q. In other words, what he's saying is if you're going to be sexually active and you're going to get the IFU Prolift, you need to be told it might potentially or occasionally lead to anatomical distortion of your vaginal cavity so much that it could interfere with sexual

intercourse; right?

MR. DAVIS: Object to the form.

A. Yes.

BY MR. WALLACE:

Q. That's what he wants to do.

And Scott Ciarrocca asked Sean O'Bryan and Charlotte Owens, "Can we do this;" right?

And they say, "We can change the adverse event to whatever is most appropriate."

Do you see that?

A. Yes.

Q. So they're saying "We can do it," but Scott says, on January 13, 2005, "We have already printed launch stock. This would be a next-rev, R-E-V, addition but they want it in there ASAP."

Do you see that?

A. Yes.

Q. You would agree with me that Scott Ciarrocca was a project leader for Prolift?

A. Yes.

Q. And that they've concluded that they can make this change to the IFU; correct?

MR. DAVIS: Object to the form.

A. Yes.

BY MR. WALLACE:

Q. But Scott decides that they're going to do it next time around; right?

A. I'm not clear what he means by, "But they want it in there ASAP." I wasn't clear what that particular extra phrase meant.

Q. Did you read his testimony?

A. You've asked me that before, and I don't recall.

Q. Okay. Do you -- do you know whether or not Ethicon actually ever incorporated what Axel Arnaud wanted in the IFU?

A. Not these exact words, but that's not uncommon.

Q. Do you think that if a medical device company is aware -- well, I've already asked you.

Isn't Ethicon failing to meet industry standards when it knows about the risk that's being identified here by one of its own employees and decides that it's not important enough to put in the IFU?

MR. DAVIS: Object to the form.

A. I cannot answer the way you've asked because you said they did not put it in there, and that they didn't want to put it in there. They did want to put it

in there.
BY MR. WALLACE:
Q. But they didn't?
A. I as a regular --
MR. DAVIS: Object to form.
A. Not in these exact words, perhaps, but when a person proposes wording to go into an instruction for use, the process for approval and for writing the -- the information into the IFU has to go through many hands; for example, someone might think it should be a warning, someone else might think it should be a caution, someone else might choose to write it a different way, but it's my understanding that that information is in the instructions for use, and that -- maybe not those exact words and perhaps not as a warning.
BY MR. WALLACE:
Q. Where's the debate that -- between the people about whether or not it should be a warning or somewhere else in the instruction for use?
A. Of course it's not in this e-mail. That takes place in meetings where regulatory people and engineers and physicians all get together and discuss how to word the instructions for use, and he says here -- what you didn't point out was he's talking about it has to be

consistent with a Gynemesh PS, because as I was talking about before, the material was used in similar procedures so they have to make that similar, and they have to make it similar -- he's talking about it would take to the second rev of Prolift. No one is saying not to put it in here.

Q. They didn't; did they?

A. Sorry?

Q. They didn't; did they?

A. The exact wording -- sir, I don't recall the exact wording, no.

Q. Would you, if you were a woman getting a Prolift, want to know if your vagina was going to be anatomically distorted?

A. You dropped your voice, I'm sorry.

Q. Would you, as a woman who was going to be possibly receiving the Prolift device, want to know, if you're sexually active, that your vagina might be anatomically distorted?

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. That's a pretty easy yes-or-no; isn't it?

A. As I understand it, sir, even a hysterectomy can do that, so it's -- the way you've asked the question,

I would want to know that a hysterectomy would do that. Of course I would want to know that, but you're asking it in a way as if someone is holding that information back from me, and that's not the case.

Q. I'm asking you very simply. I'm not talking about whether or not you're getting a hysterectomy. I'm asking you, if you were sitting down to decide whether or not you were going to receive the Prolift device and you're a sexually active woman, would you want to know whether that surgery can lead to complications which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse.

Yes or no?

A. Hypothetically speaking, I would, yes, but I can't say that this statement is a correct wording.

Q. You don't know whether or not, actually, that can happen; right?

A. I didn't say that. I said I am not qualified to speak to the terminology of the IFU for that particular medical procedure. Hypothetically, I would like to know about it.

Q. Right. So if your vagina was going to be permanently destroyed, you would want to know?

MR. DAVIS: Object to form.

A. Permanently destroyed?
BY MR. WALLACE:
Q. Right.
A. That certainly is not within the context of this. Now you're bringing in something differently -- different.
MR. WALLACE: Mark that.
(Whereupon, Exhibit 9 was marked.)
BY MR. WALLACE:
Q. You've been provided Exhibit 9; is that correct?
A. I recall reading it.
Q. And why did you read it?
A. It was in the materials.
Q. Is it, in fact, what this document -- which is an e-mail exchange between Ethicon employees and a doctor -- pointing out an anatomically distorted vagina?
A. May I read it a moment?
Q. Go ahead.
A. I have to recall.
MR. WALLACE: Off the record.
(Discussion off the record.)
BY MR. WALLACE:
Q. Have you had an opportunity to look at the

document, Ms. Duncan?

A. I'm almost finished.

MR. DAVIS: We're not going off the record. You did not allow Anne Wilson to go off the record. If she needs to look at the document --

MR. WALLACE: We're not off the record right now; we're on the record.

MR. DAVIS: I'm sorry. I apologize. I thought I heard you tell her we're off the record. I apologize.

BY MR. WALLACE:

Q. Are you done?

A. Yes, sir.

Q. Would you agree with me that the physician that is sending this e-mail to Scott Jones is describing an anatomically distorted vagina?

A. It's what the physician says.

Q. And he's saying that he's currently involved in getting a patient to the OR, meaning the operating room, who has mesh literally protruding everywhere; right?

A. It's what he wrote.

Q. And it's his opinion at the time that he's writing this that it's likely that this patient is going to lose any coital function.

Do you see that?

A. That's what he says.

Q. And that is referring to sexual intercourse; correct?

A. Yes.

Q. And he's pointing out that her vaginal space is so distorted that it's now three centimeters.

Do you see that?

A. Yes.

Q. And he is also pointing out that this patient will have a permanently destroyed vagina and that he's only hoping to get her out of this without any morbidity.

Do you see that?

MR. DAVIS: Object to the form.

A. Yes.

BY MR. WALLACE:

Q. Isn't this document describing, in very clear terms, exactly the kind of warning or event that Axel Arnaud was warning about in 2003?

MR. DAVIS: Object to the form.

A. No, sir, I cannot make that conclusion based on this particular e-mail because there's no other information about the patient other than what the physician is saying in his e-mail. There's -- there's a

lot left unsaid here.
BY MR. WALLACE:
Q. Well, this document is talking about the Prolift; right?
A. Yes.
Q. Axel Arnaud was talking about the Prolift?
A. Yes.
Q. And this physician is describing an anatomical distortion in the vagina, and Axel Arnaud was describing an anatomical distortion in the vagina; right?
MR. DAVIS: Object to the form.
A. Yes, they are describing that.
BY MR. WALLACE:
Q. And the patient -- or Axel Arnaud was saying that that could interfere with sexual intercourse; correct?
MR. DAVIS: Objection --
A. Yes, and they're also talking about training practitioners.
BY MR. WALLACE:
Q. Can I finish my question, please?
A. Yes.
Q. My question was, Axel Arnaud was describing the fact that there could be a problem with sexual

intercourse, and this physician is also saying that this lady is likely to lose the ability to have sexual intercourse; correct?

A. Yes, sir.

Q. And the fact that she's going to have a permanently-destroyed vagina?

A. Yes.

Q. So I'm going to ask my question again.

Isn't this event that's being described by this physician here with respect to the Prolift device what Axel Arnaud was warning about; that, in fact, the Prolift device could result in erosions which could result in anatomical distortion of the vagina and interfere with sexual intercourse?

MR. DAVIS: Object to the form.

A. Sir, this e-mail does not specifically state whether or not this patient had a hysterectomy, concurrent or prior. You're trying to link the two, and I don't see enough information in this e-mail to conclusively link the two as you are doing.

BY MR. WALLACE:

Q. Ma'am, you're -- I'm going to clear up the confusion for you.

Why don't you look at the e-mail because the

e-mail says that it may become more prevalent with a hysterectomy. It doesn't say that it only happens when there's an associated hysterectomy. So why don't you read Axel's warning.

Does that clear up your confusion?

MR. DAVIS: Object to the form.

A. I'm not confused. I'm not confused about these two. I'm stating that this e-mail (pointing) is separate from this e-mail (pointing) and he's --

BY MR. WALLACE:

Q. They're describing the same events; correct?

MR. DAVIS: Finish your answer before --

A. He was proposing wording of a specific warning, and the context of the warning is clear. The context of this e-mail is not clear. I don't know that this physician did this procedure. I don't know anything about this particular patient. I cannot leap from this e-mail to that e-mail. That would be inappropriate to do that.

BY MR. WALLACE:

Q. Well, you used the word "similar" before, so I'm going to use it.

Would you agree with me that, because you've already agreed with me, that this doctor has described

anatomical distortion that is interfering with sexual intercourse that, in fact, what he's describing is similar to what warning Axel Arnaud wanted to put on there?

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. Yes or no?

A. There are similarities.

Q. Now, where are all the documents where Ethicon followed up on this adverse event?

MR. DAVIS: Object to the form.

A. Did you ask me where they are?

BY MR. WALLACE:

Q. Uh-huh (affirmative).

A. I will have to go back to the documents and look for them, I suppose.

Q. Well, you said Exhibit 9 looked familiar to you; right?

A. Yes, sir.

Q. And you read it in the course of your -- what is it; 82 hours that you worked on the report?

A. I read all of the complaint.

Q. So when you read something about a woman having a permanently destroyed vagina, was -- your first thought was that this was an adverse event; right?

A. I was reading all of the complaints, trying to understand the complaints as they had been reported.

Q. And you would want to know, as someone in your position that's rendering an opinion about how thorough the company was, what the company might have done about this complaint of an adverse event by a physician; right?

A. First off, I have to say that it has to get -- we are making a presumption that this was submitted as a complaint, and then, that way, they would be able to react to it. I don't know, sitting here today looking at this e-mail, if the e-mail got through the complaint system or not. I would have to look at that. I can't just recall.

Q. Well, is this a compliment or a complaint? Is this a compliment about the Prolift or a complaint about the Prolift?

A. I just was explaining to you that an e-mail like this has to go through the complaint system, and if Scott submitted it in the complaint system, then I can track that for you. I can't sit here and tell you how it was reacted to from memory.

Q. So you don't, as a person who's opining with respect to Ethicon and giving a Rule 26 expert report, you did not say, "Listen, was this reported as a complaint or not?"

A. There were many complaints that I did not track each complaint to each response. I looked at complaint reports and how those complaint reports, which are summaries of complaints, were reacted to by the company. I recall reading this complaint, but I do not recall how this complaint filtered through the system. I would have to check that for you. I can't recall that.

Q. You would agree with me that the company, upon receiving this information, should have put this through the complaint process; right?

A. I would assume that it would have gone through the complaint system, but I would have to check that.

Q. And one of the things that companies can do is they can reach out to physicians, for example, to get explanted material or try to work with those physicians as much as possible to understand why complications are occurring; right?

MR. DAVIS: Object to the form.

A. They do and can, yes.

BY MR. WALLACE:

Q. And Ethicon had the opportunity, like other medical device manufacturers, to actually reach out to physicians to try to get those implants back if at all possible?

MR. DAVIS: Object to the form.

A. I don't know what their opportunities were. They could have asked. I don't know what real opportunities exist because if this was outside the country, I can't recall exactly the location for Dr. Long, but some countries do not allow them to be -- to leave their country. Some hospitals will not release the samples. I don't know what opportunities they had to get this back.

BY MR. WALLACE:

Q. Well, my read of the e-mail is that Scott Jones makes it very clear that he's e-mailing St. Louis University Uro-GYN, and the e-mail is from a St. Louis University address.

A. But I'm saying -- you were speaking generally. I do not know specifically what they were able to do.

Q. With respect to the adverse event -- let me back up for a second and then we'll take a break.

You have given the opinion that Ethicon's follow-up on its adverse events was thorough and appropriate; correct?

A. I was -- I believe that I was speaking of the design control and review and the risk analysis and the risk management after the project was in the market.

Q. And with respect to the risk management that was done after the products were in the market, those products, by the way, being the Prolift, the Prolift+M and the Prosima, it is your opinion that Ethicon did a thorough job in following up on adverse event reports after the product was released to the market?

A. Yes, sir.

Q. And tell me where there is any evidence whatsoever in any of your documents or anywhere, for that matter, that Ethicon attempted to get explanted material back in order to determine or examine complications with respect to those medical devices.

MR. DAVIS: Object to the form.

A. With respect to numerous complaints that I read and MDR reports that I read that followed from those serious complaints, basically a serious adverse event would engender a complaint -- excuse me, an MDR -- as a part of that process, the personnel asked for the implant to be returned when they're doing their follow-up. Individual people within a company may not have that privilege. That's usually delegated to the person in the complaint department who's following up on an adverse event that's reportable under MDR. So they seek out additional information about the event so that they can be

more thorough in their MDR reporting, and that that is their opportunity to ask if the implant will be returned.

MR. WALLACE: Take a break?

MR. DAVIS: Sure.

(Whereupon, a recess was taken from 12:24 p.m. to 12:34 p.m.)

(Whereupon, Exhibit 10 was marked.)

BY MR. WALLACE:

Q. Have you seen that document before?

A. Yes.

Q. Do you know who -- I wish I could tell you the page number, but let me ask you some names.

Do you know -- can you read German?

A. I cannot read German.

Q. What do the first 18 pages represent?

A. These two pages?

Q. No, the first 18?

A. 18, oh.

Q. Are in German; correct?

MR. DAVIS: Object to the form.

A. Yes.

BY MR. WALLACE:

Q. Can you read them?

A. I can tell you they are a procedure, and

there's a couple of places where they are dual-translated so I can get enough out of this to understand what it's about.

Q. What do you understand this exhibit to represent?

A. That this is a risk analysis procedure.

Q. By whom?

A. The Norderstedt location; is that what you mean? The author was Dr. Hinsch. It says "Reviser." I don't know exactly what that means.

Q. Can I -- let me ask a more simple question.

Does Exhibit 10 have any relevance to your opinions whatsoever?

A. Yes.

Q. In what way?

A. This was a procedure for the conduct of the risk analysis that was conducted at Norderstedt.

Q. And you would agree with me that it cites 1441?

A. In the appendix, they -- they list the appendices, but they're not attached here, of course, but in the appendices, they refer to EN 1441.

Q. And you would agree with me that Anne Wilson believes that that applied to the company?

MR. DAVIS: Object to the form.

A. Sir, I don't know -- excuse me?

BY MR. WALLACE:

Q. Let's back up for a second.

You would agree with me that 1441 is an international standard; correct?

A. It was actually an EN standard.

Q. And what do you mean by that?

A. It was a European national standard.

Q. Well, that's international; right?

MR. DAVIS: Object to the form.

A. Outside of the U.S., it is, beyond our borders.

BY MR. WALLACE:

Q. I don't want to quibble with you about whether it's international or European, but the bottom line is it was a standard that was applied to Ethicon, and Ethicon believed that this standard applied to it; correct?

MR. DAVIS: Object to the form.

A. The second way you said that is correct; Ethicon believed that it was applicable. It is a voluntary standard, so it is not applied to a company.

BY MR. WALLACE:

Q. Ethicon adopted the 1441 standard?

A. At a certain point in time, they did.

Q. You can put that to the side.

(Whereupon, Exhibit 11 was marked.)

BY MR. WALLACE:

Q. You -- I'll represent to you that on page 12 of your report, you refer to Exhibit 11, which is a biocompatibility risk assessment from the PROLENE technical file.

Do you recall footnoting or referencing this document?

A. It looks familiar, yes.

Q. And it's signed by Thomas Barbolt, that's spelled B-A-R-B-O-L-T; right?

A. Yes.

Q. And you cite to this document to make the point that PROLENE was a successful suture device that had an accepted indication for use; correct?

A. I would -- you're speaking of what I said?

Q. Yeah.

A. What page is that, please?

Q. On page 12. You said that PROLENE was successfully developed as a biomaterial.

A. It's a suture biomaterial in the 1960s.

Q. Right. Just to be clear, you're referring to

a suture, not a vaginal mesh; right?

A. In that sentence, I'm speaking of a suture.

Q. And you would agree with me that the document you referred to, which is Exhibit 11, was signed by Thomas Barbolt?

A. Okay. And excuse me, again, what was the footnote you referenced?

Q. Footnote 9.

A. 9, okay.

Q. If you look at the second page of Exhibit 11, you'll see the signature of Thomas Barbolt.

Do you see that?

A. Yes, sir.

Q. Do you recall reading his testimony in this case?

A. I recall reading it, but I can't recall exact words.

Q. Well, let me ask you this way, then.

If he testified that PROLENE is susceptible to surface degradation, you wouldn't have any reason to disagree with him; right?

A. Is that another hypothetical? I don't recall his exact testimony, so if you want to read that to me, I can tell you if I agree or disagree.

Q. I -- I get to ask the questions this way, though.

A. Okay.

Q. So I'm going to ask -- it's a very basic question.

If he testified --

A. If he testified?

Q. -- if he testified that PROLENE is susceptible to surface degradation, you wouldn't have any reason to disagree with that testimony; would you?

A. If he testified, I would not disagree with that statement.

Q. Okay. And did any of the testing that is referenced or materials that are referenced in Exhibit 11 have anything to do with evaluating the performance of PROLENE in the pelvic floor?

MR. DAVIS: You're pointing her to Exhibit 11?

THE WITNESS: I can't make out the date.

MR. DAVIS: 1997.

THE WITNESS: This is 1997?

BY MR. WALLACE:

Q. Page 2, yes. Just for the record, you've written on the exhibit.

A. I'm sorry.

Q. That's okay. That's fine if you want to do that. That's not a problem for me.

I take it you're trying to reference the date because you want to know if this predates the pelvic floor repair kits; right?

A. You introduced that point.

Q. Okay. So you would agree with me that, with respect to Exhibit 11, that the materials or other information, including the literature that's referenced in Exhibit 11, do not evaluate the performance of PROLENE in the pelvic floor?

A. On page 33, he references an implant, and I just need a moment to look at this. And your question again, please repeat.

Q. The information and literature referenced in Exhibit 11 does not reference the use of PROLENE in the pelvic floor.

A. On page 35, the reference is to colposuspension and urinary incontinence, rectopexy, colposacropexy. So in some respects, I see it as being pertinent to the general use in -- in pelvic floor, but not specific to these devices as they are created in the Prolift and the Prosima.

Q. Thank you. You can put that to the side.

A. Okay.

Q. You -- with respect to the issue of degradation, you noted that FDA inspection showed no deficiency had been observed with respect to the risk analysis relating to degradation.

Is it fair to say that you can't offer your opinions in this case without reference to FDA regulations?

MR. DAVIS: Object to the form.

A. No, sir. Can you say -- can you cite to the location in the report, please?

BY MR. WALLACE:

Q. I think it was page 21, if I'm not mistaken, but I'm just asking a more general question, ma'am.

What I'm saying is you say that -- and I'm going to generalize what you say in the report -- that you can't take into account device design and risk assessment without considering the FDA regulations that you believe apply to it; right?

MR. DAVIS: Object to the form; asked and answered, calls for speculation.

A. No, not correct.

BY MR. WALLACE:

Q. Why aren't I correct?

A. Because the review I did incorporated the requirements in both a specific and a general sense.

Q. What do you mean by that?

A. I looked at requirements that were, for example, standards that were referenced and considered by the groups that were internationally located, as well as the clearance requirements for selling the product in the U.S. So all of those were part of my review.

Q. Fair enough. I appreciate you clearing that up. What I'm getting at is that what you believe applies here are standards that are recommended or required by regulatory bodies; right?

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. Whether they be European or FDA?

A. Not all of the applicable standards at any given time are adopted by each of these organizations, so you have to -- so it's difficult, when you ask me a general question, for me to give you a general answer. We have to look at when the standards were applicable in each of these countries.

Q. You spent a lot of time talking about the 510(k) process, for example.

Do you believe that your opinion is based on -- can exist with or without references to 510(k)?

A. Yes, I believe I can make the -- the report without reference to the 510(k).

Q. Do you believe that you can make this report without references to any FDA regulations whatsoever?

A. I would be remiss if I knew that there was an issue with regulatory clearance in any jurisdiction and didn't bring it up in the report.

Q. Why?

A. Because it was a part of my due diligence in the review of the documentation.

Q. And you think that affects how the company would conduct its analysis of risk, for example?

MR. DAVIS: Object to the form.

A. For example, in 14971, the standard admonishes you to take into consideration, when conducting a risk analysis, the prevailing regulatory requirements in the respective jurisdiction. That's in the 14971. So if I'm looking at how somebody does the risk analysis, I have to do that in the perspective as the standard directs me to appreciate regulatory requirements on it.

Is -- is that clear?

BY MR. WALLACE:

Q. Well, it's your opinion on page 21, for example, that the safety of the product is intertwined with quality systems that must meet the requirements established by regulatory authorities.

Do you see that?

A. Do you have a specific paragraph?

Q. The fourth full paragraph down.

A. Starting with Dr. Dunn?

Q. Yes. What I'm understanding -- I'm just telling you what I'm understanding reading your report is that you cannot -- you can't give me your opinions without referencing the requirements established by regulatory authorities.

MR. DAVIS: Object to the form.

A. I disagree with your statement. I'm -- on page 21, I'm speaking specifically to what Dr. Dunn had said. This is part of the report that is, if you will, a rebuttal to his claims, and so I'm commenting on his accusation that Ethicon has an inadequate quality system. He stated that, and I'm countering that I believe he doesn't understand the scope of their quality system.

So when I'm discussing that, there's two bullet points I speak of; the quality systems associated with one of the primary jurisdictions, the U.S., and the

other primary jurisdiction, Europe, and I'm pointing out that his claim is incorrect. That's what I'm saying in this report.

BY MR. WALLACE:

Q. Let's -- you can put that document away for a moment.

You would agree with me that when a company decides to launch a product like the Prolift, that they need to understand how wound healing occurs in the space in which the device is going to be implanted; right?

A. That's correct.

Q. And they need to understand how, if they're working with different grafts, like the Prolift or the Prolift+M or Prosima, how those devices might compare to each other as to their performance in that space; right?

A. The question contains a premise that I need you to clarify. The Prosima and the Prolift, differences are primarily the instrumentation, so the material in that space would not be different in its healing characteristics.

Q. If you want to limit your answer to the Prolift and the Prolift+M, go ahead.

A. But your question --

Q. They want to see how different grafts are

going to perform in the space; right?

A. I don't characterize this as a graft, but if -- that's your word. It's a scaffold.

Q. Would you agree with me that the mesh at issue has pores to allegedly allow for tissue ingrowth?

A. Yes, sir.

Q. And you would agree with me that before this product is launched, that the company needs to understand the importance of pore size and how the mesh is going to integrate with the tissue; right?

A. That's correct.

Q. And you would agree with me that if there are issues about flexibility or elasticity, that the company needs to understand that before it launches the product for sale; correct?

MR. DAVIS: Object to the form.

A. As I pointed out, the PROLENE Soft Mesh design team considered the flexibility issue as a part of their design requirements.

BY MR. WALLACE:

Q. Do you believe that the company needs to be familiar with the applicable medical and scientific literature that may relate to the device before that device is launched?

A. Yes, sir.

Q. All right.

(Whereupon, Exhibit 12 was marked.)

BY MR. WALLACE:

Q. Have you seen that document before, which is Exhibit 12?

A. Let me read it a moment. They all tend to blur together.

Q. And my question remains pending, that whether or not you've seen this document before. That's all I want to know.

A. It's not that familiar to me, but --

Q. Is it possible that you could have seen it before?

A. It's possible I've read it, but I can't recall.

Q. Do you know who Jonathan Meek is?

A. I recall his name, but I can't place his position in the company.

Q. Do you know who Piet Hinoul, P-I-E-T, Hinoul, H-I-N-O-U-L?

Do you know who he is?

A. Jonathan Meek, the worldwide director, sure, I'm recognizing him, yes. Like I said, I'm not recalling.

Q. What about Mr. Kirkemo; do you remember who he is?

A. Don't remember his title, but I remember reading his and -- how do you say it; Piet Hinoul?

Q. Uh-huh (affirmative).

A. Yes. Harel Gadot, yes.

Q. Let me ask you a different question.

A. These names are familiar, yes.

Q. Okay. So you're familiar with the names on the e-mail?

A. Yes, yes.

Q. And you would agree with me that's an October 29 -- I'm sorry, October 29, 2008 e-mail; right?

A. Yes.

Q. And that Mr. Meek is saying that they're -- that he's getting the team together to discuss the pre-reading that will support the knowledge build for the Prolift+M launch, and he admits that he was ignorant to the work carried out by the likes of Cobb, Klosterfalfen and Klinge, Klosterfalfen being spelled K-L-O-S-T-E-R-F-A-L-F-E-N; right?

A. Yes.

Q. Do you see that?

A. Yes.

Q. Are you aware of the literature that Dr. Klosterfalfen published in 2000 about adverse events relating to mesh?

A. I believe I read that paper.

Q. Did you read the paper authored by Dr. Cobb from 2004?

A. I'm not as familiar with that name.

Q. Are you familiar with Dr. Klinge's work which has spanned, at this point, well over a decade?

A. I'm familiar. I've read a number of papers.

Q. Would you think that it's important that someone that is working on the Prolift M in the position that Mr. Meek was as a worldwide marketing director who would be describing the attributes of the product to be familiar with the properties of the device?

MR. DAVIS: Object to the form.

A. Properties of the device?

BY MR. WALLACE:

Q. (Nodding head.)

A. Which device are you speaking of? All of the devices?

Q. The Prolift and the Prolift+M.

A. I would think he would be generally familiar. I don't know that he'd be able to recall physical

properties to the letter, but generally knowledgeable.

Q. Does it surprise you that he was ignorant to the work carried out by these physicians?

MR. DAVIS: Object to the form.

A. Frankly, no, because, as I recall, at least some of this work was in the biomaterials research area and not in clinical work, and so it's not out of the question that specific pockets of research don't filter up to clinical work.

BY MR. WALLACE:

Q. You would agree with me that one of the concepts in this exhibit that we looked at quite a while back, Exhibit 6, was that they wanted to have the best procedure.

Do you recall seeing that?

A. Generally, it was -- yes, it was a safe -- that was one of their objectives, of course.

Q. That it was going to be the best of the best; right?

A. The best -- I don't recall those exact words.

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. I'll find it for you.

Here you go. Look at page 39 of Exhibit 6 and

tell me, when they're assessing the market, that they want to employ the approach of the best product and the best procedure.

A. He says this, yes.

Q. That's what the concept document says in Exhibit 6?

A. Yes, the market assessment in the EU, their opportunity is to have the best product and the best procedure.

Q. And you would agree with me that that's, of course, what any responsible medical device manufacturer would want to do in the United States, as well; is to have the best product available and the best procedure, if possible; right?

A. Yes.

Q. And if you're making a marketing claim in that regard, you want to be, of course, truthful and accurate; right?

A. Yes. Did they make that claim?

Q. Can you then, please, look at Exhibit 12 and look at the key point at the bottom of the page?

A. Okay.

Q. And it says, "PP --" which I'll represent to you stands for polypropylene "-- is the best of a bad lot

re integration, retraction, and there is a need to develop grafts that mimic the human tissue and mechanical properties."

Do you see that?

A. Yes.

Q. And do you believe that Mr. Meek was being truthful and accurate at the time that he wrote that internal e-mail?

MR. DAVIS: Object to the form.

A. I don't know what he meant, but I don't think that anybody was arguing at that point in time that they were seeking a material with better human tissue mechanical properties. That was -- that's been a quest for 20 years.

BY MR. WALLACE:

Q. Do you know whether or not Ethicon told physicians and patients that polypropylene was the best of a bad lot regarding integration and retraction?

MR. DAVIS: Object to the form.

A. I don't know if anyone would use that terminology.

BY MR. WALLACE:

Q. Do you -- have you seen -- we've talked about pore size already; right?

A. No, we haven't.

Q. Okay. Well, let's talk about it for a moment.

You would agree with me that an effective pore size is important for tissue ingrowth in the Prolift and the other products you're here to testify about; right?

A. Yes, pore size is a consideration.

Q. And you would agree with me that these products, especially the arms being placed under stress and tension, that you would have to do some analysis as to how pore size might be affected upon implant in order to allow adequate tissue ingrowth; right?

MR. DAVIS: Object to the form.

A. That would be one attribute.

BY MR. WALLACE:

Q. And the company would want to look at that; right?

A. That would be one attribute, yes.

Q. And do you say anywhere in your report, at all, or cite to any documents where the company actually considered how effective pore size might be in these products after implant?

MR. DAVIS: Object to the form.

A. My recall is that a part of the PROLENE Soft development was to assess the properties of pores and also

how pores change under tension, and I can't recall exactly where that discussion was. I'd have to look it up.

BY MR. WALLACE:

Q. You would agree with me, though, when you're talking about PROLENE generally, that PROLENE doesn't have pores?

A. Excuse me? Say it again.

Q. PROLENE does not have pores. A PROLENE suture does not have pores; does it?

A. Oh, a PROLENE suture is not porous. There were PROLENE twist -- let me -- what's the term? PROLENE, as we're describing it, is a monofilament. There was a multi-filament PROLENE suture.

Q. I'm going to mark this document and ask that you flip to page 7.

(Whereupon, Exhibit 13 was marked.)

BY MR. WALLACE:

Q. You cited this document, didn't you, for the proposition that others, including the FDA, have said that the use of PROLENE as an implant is safe; correct?

A. I would like to see how I cited it. Would you -- do you recall? I'd have to look them up.

Q. You don't remember citing to that document?

A. I remember citing the document, but there are

so many documents in here.

Q. Page 26.

A. Okay. Thank you.

Q. You actually -- you're quoting from the document, but you don't cite it. I'll represent that to you.

A. I'm sorry?

Q. You're quoting from -- from this document. You actually don't cite it, ma'am, but you're quoting from it. I'll represent that to you; okay?

What I want to know --

A. Where do you say that I'm quoting from it?

Q. "By 1990." I assume you're referencing this document.

MR. DAVIS: He's pointing to right down there (pointing).

THE WITNESS: Oh.

BY MR. WALLACE:

Q. Are you or are you not referring to this document?

A. I wasn't specific to that document, but that certainly is one of the many documents.

Q. Well, just real quickly, you would agree with me that the -- if you look at page 8 of this document,

that the type of tissue at the wound site and where the device is actually going to be placed matter, and you, as a biomedical engineer, know that that is a very critical consideration that a company has to take into account when designing a device; correct?

A. Correct.

Q. So the fact that the use of a suture without pores is safe and effective, say for example, in somebody's arm or in somebody's heart, doesn't necessarily mean that it's safe when it's woven together as a transvaginal mesh and placed inside a woman's transvaginal tissues; right?

MR. DAVIS: Object to the form.

A. I disagree with what you are characterizing as what I said. I didn't say that. I said it was already well-known and studied that it had been tolerated within the human body and that any oxidative degradation proceeds slowly and it's not clinically significant, and that's what I was speaking of. I didn't leap from there to other locations.

BY MR. WALLACE:

Q. I'm just asking you generally, you can't sit here today and testify that, because the FDA made a statement in 1990 that oxidation proceeds slowly with

respect to a suture, that it proceeds slowly with respect to a transvaginal mesh placed inside a woman's vaginal tissues; right?

A. I can't say to the contrary, either. I cannot answer the question as -- as you have proposed it.

Q. Who has the burden to prove that their device is safe?

A. The company putting it on the market.

Q. Okay. And so -- and you would agree with me --

MR. DAVIS: Object to form on that last question.

BY MR. WALLACE:

Q. Let's just move on.

You recall testifying before; right?

A. Yes.

Q. And we were in the room next door, I think.

A. Okay.

Q. And you, both in this report and at your deposition back then, in my words -- not yours -- made it a pretty big deal that the FDA had made some, what you believe to be, favorable statements about the use of mesh, right?

MR. DAVIS: Object to the form.

A. I believe I referenced the AUGS statement, A-U-G-S.

BY MR. WALLACE:

Q. Well, you -- you also referenced the FDA in your deposition before. You said -- you referenced the AUGS Organization, and even the FDA that, "I would be foolhardy to suggest that there was a better way to make this product."

Do you recall making, generally, a statement like that?

A. I don't recall that exact wording. If you want to read it to me, I don't --

Q. Well, let me ask you generally.

You would agree with me that you have taken into account what the FDA has done in the past with respect to both mesh and PROLENE in coming up with your opinions; right?

MR. DAVIS: Object to the form.

A. I've taken into account all aspects of the use of the material, including hernia applications, and so that would include any regulatory approvals in any country.

BY MR. WALLACE:

Q. And I'm getting at something much more simpler

that shouldn't really be in debate.

A. Okay.

Q. You took into account all the documents that you reviewed, and you also took into account what the FDA had to say about them; right?

A. Oh, I recall. There was an FDA release, news release where they accepted the TVT product from their 522 order.

Q. And that was relevant to your opinion; right?

A. At the time.

Q. Okay.

A. Because we were discussing the TVT product at the time.

Q. Well, if the FDA identified surgical mesh for transvaginal repair of pelvic organ prolapse as an area of serious concern, would that be something that you would consider and take into account when rendering an opinion?

A. You have to consider any organization of that nature that would make a pronouncement of that sort.

Q. Well, does that affect your view of the safety of POP devices?

MR. DAVIS: Object to the form.

A. No, it has not.

MR. WALLACE: I think we're going to

switch seats for the time being.

MS. FITZPATRICK: You may want to take a brief break.

(Whereupon, a recess was taken from 1:11 p.m. to 1:14 p.m.)

EXAMINATION

BY MS. FITZPATRICK:

Q. Ms. Duncan, my name is Fidelma Fitzpatrick. We met a number of months ago here.

Do you recall?

A. Yes.

Q. And at that point, I took your deposition on the TVT retropubic device.

A. Yes, sir -- ma'am.

Q. And that was in conjunction with a case that was pending in the Southern District of West Virginia -- actually, 37 cases pending there; correct?

A. Yes, ma'am.

Q. And since that time, you have issued a report on the TVT retropubic and the TVT-O devices; correct?

A. Yes, ma'am.

Q. So I'm going to go ahead and get these marked as -- Exhibit 14 will be the TVT-R report, and the Exhibit 15 will be the TVT0 report.

MS. FITZPATRICK: Do you need a copy?

MR. DAVIS: Those two, I do already have a copy.

MS. FITZPATRICK: I got them for you here if you want them.

(Whereupon, Exhibits 14 and 15 were marked.)

BY MS. FITZPATRICK:

Q. So there's the marked copies.

Now, have you had a chance to look at your TVT-R deposition that I took a number of months ago?

A. I read it some time ago.

Q. And is there anything in that deposition that you need to change or alter in any way? I don't want to rehash old ground.

MR. DAVIS: Just one technicality; you mean other than the errata sheet she's already given?

BY MS. FITZPATRICK:

Q. Other than the errata sheet that you've already given; correct.

A. Yes, I can't recall if we found any other typos on footnotes, but I believe we caught the majority. That was the only thing.

Q. And have you changed your opinions in any way concerning the TVT-R device from the time you issued that

report until the time we're sitting here today?

A. No, ma'am.

Q. Okay. I'm going to focus primarily, given the limited amount of time, on the TVT-O device.

A. All right.

Q. But before I get there, you know Ethicon makes a number of stress urinary incontinence devices that are called the TVT family of devices; correct?

A. Yes.

Q. And that includes the TVT Retropubic; correct?

A. Yes.

Q. The TVT Obturator, the TVT-O?

A. Yes.

Q. The TVT Secur, TVT-S?

A. Yes.

Q. The Exact?

A. Yes.

Q. And the Abbrevo; correct?

A. Yes.

Q. And the two products that you have issued reports for in connection with these WAVE 1 cases are the TVT-R, or the retropubic, and the TVT-O, the transobturator?

A. Yes.

Q. And you have not issued and do not hold opinions on any of the other products; correct?

A. That's correct.

Q. Okay. And you'll agree with me that a medical device manufacturer has a responsibility to design their product so as to minimize the potential for injury to patients; correct?

A. That's correct.

Q. And that -- you'll agree with me that, in order to do that, a device manufacturer must consider and understand the medical condition that the device is designed to treat; correct?

A. That's correct.

Q. And it must also consider and understand the anatomical location where that device is implanted; correct?

A. That's correct.

Q. Where is a TVT-R device implanted?

A. As I understand it -- and I may speak very generically -- that it is in the same location but different -- in a different way of implanting than the TVT-O.

Q. Okay.

A. One's inside-out and the other's outside-in.

That's my basic understanding.

Q. Okay. But it's your understanding that the implant site for both the TVT-R and the TVT-O are the same?

A. That's my understanding.

Q. Okay. Did anyone at Ethicon ever tell you that?

A. I can't recall. I believe I read that.

Q. Okay. Did you look at the instructions for use on where the two products were implanted?

A. Yes. That was the best of my recall.

Q. Do you know what the obturator space is?

A. Vaguely, anatomically, yes.

Q. Okay. Sitting here today, do you understand that the TVT Retropubic and the TVT Obturator are implanted into different locations in a woman's pelvis?

A. It was my understanding that the mesh material, essentially, winds up, more or less, in the same location.

Q. Okay. And is that understanding that you have concerning the two devices, did that factor into the opinions that you gave in this case and the reports identified as 14 and 15?

A. I would have to say yes, it did.

Q. Okay. And you agree with me that it's important, when you are designing a device or doing -- scratch that.

You'll agree with me that it's important, when you're doing a risk assessment of a device, to understand where the device is going to be placed in the body; correct?

A. Yes.

Q. And you'll agree with me that it's important to understand the surgical approach that's going to be used to implant those different devices; correct?

A. Yes, and that's what I tried to understand.

Q. Okay. And you tried to understand that based on the documents that you looked at and identified in your reliance list?

A. Yes.

Q. Okay. Did you understand when you put -- do you have any understanding of whether the trocars that are used to implant the TVT-R are the same or different than the trocars that are used to implant the TVT-O?

A. It's my understanding that the TVT-O trocars are somewhat different.

Q. Okay. And they are a different shape; correct?

A. Yes.

Q. And that's used because there's a different surgical placement of the TVT-O over the TVT-R; correct?

A. It was my understanding that it was because of the surgical approach.

Q. Okay. And when you say surgical approach, are you referring to what you call the inside-out versus the outside-in approach?

A. Yes.

Q. And so it's your understanding that the trocars -- well, first of all, which one of these is implanted with the inside-out approach; do you recall?

A. Yes.

Q. Okay.

A. The TVT-O.

Q. Okay. Inside-out, let me ask if we're on the same page. Inside-out is when you go in through the vagina and you put the trocars out of the pelvis by introducing it through the vagina first?

A. That's my understanding.

Q. Okay. And the outside-in approach that you believe is used with the TVT-R is when you go from the outer area in the abdomen or the pelvis and you push the trocars through into the vagina and then pull them up

again; correct?

A. That's right.

Q. And it's your understanding that those different approaches, the inside-out versus the outside-in, are what account for the different shapes of the trocars that are used with the TVT-R and the TVT-O procedure?

A. That's my perception from reading the documents I read.

Q. Okay. And you took that -- those -- the difference in the trocars on the outside-in and the inside-out approach into account when you were preparing your reports on these two devices; correct?

A. Yes.

Q. Okay. I'm going to skip --

A. Not in a specific way of my judgment of their design, good or bad, but that they needed to be shaped differently because of the procedure.

Q. Okay. And since you're not opining on the TVT-S or the Exact or Abbrevo, we've short-circuited some of my exam today, so that's good.

And you'll agree with me that a medical device manufacturer, when making a permanent device for implant into the human body, has to be an expert on the material

that is being used with the product itself; correct?

A. They have to be knowledgeable and qualify the material, yes.

Q. And they have to be experts in the design of a product for a permanent medical implant; correct?

A. Yes.

Q. Okay. And they need to be experts in the anatomical location of where the product is intended to be placed?

A. No, and let me qualify. I don't know that they have to be specifically experts in the sense of an anatomist or a physician, but they certainly have to seek that expertise as a part of their design review.

Q. So fair enough. So let me ask you this a little bit differently.

When you're putting together a design team, a medical device manufacturer would need to consult with an expert on the particular anatomical location into which a permanent medical device was going to be implanted; right?

A. That's correct.

Q. And would have to seek out clinical advice or clinical information concerning the surgical procedure that was to be used by the product?

A. Yes. For the product, yes.

Q. For the product and the surgical devices that will be used by the product; correct?

A. Are you speaking of in association at the same time in the procedure? Is that what you mean by your question?

Q. Well, okay. Let me ask it a little bit differently.

The TVT-R and the TVT-O we've discussed had different trocars?

A. Yes.

Q. Ethicon needed to consult clinicians to understand the implications of using those different trocars with these procedures; correct?

A. Correct.

Q. And a medical device manufacturer, like Ethicon, has to consider the potential severity of a failure of this product, the effect of a failure of the product on a woman; correct?

A. That would be correct, in a general statement, yes.

Q. All right. And would also have to take into account the potential frequency of a complication associated with a product; correct?

A. That's correct.

Q. And they would need to take into account the potential for the permanence of a failure of their particular product; right?

A. Excuse me for -- I need to clarify. Permanence of --

Q. Permanence of a complication.

A. Permanence of the complication. I believe that would be true.

Q. And would you agree with me that severity, frequency and permanence are three issues that need to be -- each need to be considered when assessing the particular risk from a device?

A. No in the way you spoke of it because you're duplicating it, as I see it. So severity and then you said permanence. So the severity is incorporated in -- excuse me, the permanence of the complication would be included in the risk assessment for severity. So you've added a third item that I think is incorporated into the term "severity."

Q. Okay. But you'll agree with me that you could have a permanent complication that is not particularly severe; correct?

A. I -- that's hypothetical. I don't know exactly what you might be speaking of.

Q. Okay. Well, let me maybe ask it in the --
You could have a severe complication that arises from the use of a medical device that's not a permanent complication; correct?
A. Typically, they -- such -- such an adverse event would be scored lower in the -- in the risk analysis.
Q. Okay.
A. A transient -- a transient risk would be scored less severely but not always.
Q. Okay. So all I was trying to get at is there's the severity of how bad the complication would be.
A. Yes.
Q. There's a consideration of whether it's a transient complication versus a permanent complication; correct?
A. Which kind of goes with the bad, yes.
Q. Right. And then, how often that complication, the frequency of that complication?
A. That's correct.
Q. Okay. And it's your opinion, sitting here today, that Ethicon performed an appropriate risk assessment in 2003 on its TVT-O device before it went on the market; correct?

A. I believe, in my review of it, that they did, yes.

Q. Okay. And it's also your opinion sitting here today that, after the launch of that product, Ethicon continued to engage in appropriate risk assessments through today, 2016, in association with its TVT-O product; correct?

A. Yes.

Q. And there's different ways to do risk assessment; aren't there?

A. Yes.

Q. And one of those ways can be through what is called an FMEA?

A. Yes, ma'am.

Q. And I think last time we were here, we talked about the different kinds of FMEAs that could be used, so I don't want to rehash that.

But you'll agree with me that Ethicon chose to use FMEAs as one of its ways to conduct risk analysis on the TVT-O device?

A. Yes.

Q. You've had a chance to look at Dr. Wilson's report, and actually, you provided some criticisms to that report; is that right?

MR. DAVIS: Object to the form.

A. I didn't realize Anne was a doctor, but yes.

BY MS. FITZPATRICK:

Q. Okay. And one of the things that -- that Ms. Wilson said was that Ethicon's own procedures required that if a similar device is used for risk assessment instead of the actual device, Ethicon had to demonstrate that the changes that had been made to the system would not introduce significant differences in the results of the risk assessment.

Do you agree, in principle, with that statement? And I apologize, I don't have a copy of her report in front of me. I used to have one. If you have one, I can --

MR. DAVIS: Talking about Anne Wilson's report?

MS. FITZPATRICK: Yeah.

MR. DAVIS: I'll be glad -- I think I've got a copy somewhere. Which report are you referring to; the TVT-O?

MS. FITZPATRICK: TVT-O.

MR. DAVIS: TVT-O? As long as you don't mind, you know, I may -- I may have some notes.

MS. FITZPATRICK: I just want -- you

know, it's just easier for her to look at the sentence in context.

MR. DAVIS: I don't mind her looking at my copy.

THE WITNESS: This is Anne's original report; right?

MR. DAVIS: TVT-O report.

BY MS. FITZPATRICK:

Q. I think it's the -- I'm pretty sure that it is on page 14, but let me just pull it up here. I'm sorry, page 11, and I'm just looking at the bottom full paragraph. I'm asking you if you agree with the first sentence of that paragraph, in principle?

A. She hasn't footnoted the procedure that she's speaking of.

Q. Do you --

A. So I --

Q. So you don't -- you can't agree or disagree with this statement? Does this reflect your understanding of Ethicon's procedures, or not?

A. These are the procedures that I've reviewed, and every one of these procedures has different revisions.

Q. Okay.

A. And so, when I speak of these procedures, I

have to have a context of the time and the location for these procedures. And so, in Anne's statement here, she's not given us any way to go and -- and confirm her statement.

Q. Okay.

A. If I recall that they --

Q. So you don't agree -- you don't believe that Ethicon had a procedure in place that stated that if a similar device system is used for the risk assessment instead of the actual device, the team must demonstrate that the changes that have been made to the system will not introduce significant difference in the results of the risk assessment?

MR. DAVIS: Object to the form.

BY MS. FITZPATRICK:

Q. I'm just wondering whether you agree or disagree with it?

MR. DAVIS: Object to the form.

A. Yes, I agree that it's reasonable that they would do that because that is the charge of various standards, but I can't confirm Anne's statement on page 11 because I don't -- I don't know.

BY MS. FITZPATRICK:

Q. So fair enough. You -- you agree that the

concept is reasonable, but you don't know whether Ethicon had a procedure that implemented that concept; is that right?

A. Precisely.

Q. Okay. But you will agree with me that that concept is reasonable and expected in your line of work; right?

A. That's correct.

Q. Okay. Now, Ms. Wilson also identified some key differences between the TVT-R and the TVT-O.

Do you agree with her that there was a difference in the technique and points of fixation for the TVT-R and the TVT-O device?

A. It's my understanding that that is the purpose of the TVT-O.

Q. Okay. So you agree that there was a difference in them?

A. Yes.

Q. Okay. And she also identified a difference as implantation through the obturator membrane.

Do you agree with that?

A. Yes.

Q. Being a difference in the procedures?

A. I agree with that.

Q. Okay. And do you agree that the mesh ends designed to accommodate the -- let me just put it in simpler terms, I think -- that the trocars are different between the two devices?

A. Trocars are different.

Q. Okay. Now, can you point me, sitting here today, to any document in which Ethicon conducted a risk assessment prior to the launch of the TVT-O that independently identified -- or excuse me, independently addressed the differences in the risks posed by the TVT-R trocars versus the TVT-O trocars?

A. It's my recall, but I would have to look at some documents. Would -- would you like for me to try to locate one?

Q. Well, let me ask you, it's your recall that there was a risk assessment that was done by Ethicon that looked at what new and independent risks would be posed by the TVT-O trocar over the TVT-R trocar?

A. Yes, I cannot recall if it was an FMEA style or if it was a general part of the design history record. I -- I'm rather vague in terms of the actual document.

Q. How long would it take you? Because I know we're under a time frame and I know you need to get out of here. So how long do you think it would take you to go

through these several binders that you have here to find that?

A. Less than 10 minutes.

Q. Okay. I'm going to -- I think I'm going to find a list of these things that I want you to find, and then I'm going to ask you to look for all of them at the same time. I think that might be a little bit easier for us to do that way.

A. If you'd like to try that, I'll do my best.

Q. Okay. And I appreciate that.

And do you know of any document or risk assessment in which Ethicon conducted -- scratch that. That's a bad question.

Can you show me any document in which Ethicon conducted a risk assessment that independently assessed the risks associated with the implantation of the TVT-O through the obturator membrane?

A. Independently assessed the TVT-O?

Q. Uh-huh (affirmative).

A. I believe that's the same question you had asked.

Q. No, what I was asking, if you had seen anything that looked specifically at the risks posed by the TVT-O trocar?

A. Oh, trocar versus --

Q. Versus, and then the second I'm asking is if you know any document that looks specifically at the risks of the surgical implantation site of the TVT-O versus the TVT-R?

A. Again, it's my recall that there is such a document, yes.

Q. Okay. You think that there's a document that supports both of those; right?

A. Yes.

Q. Okay. And are you -- well, let me -- let me -- you know what? Why don't you go ahead and find those documents for us because that will help us get through the other questions a lot quicker.

A. First I've got to do it this way.

MS. FITZPATRICK: I want to take a quick break.

(Whereupon, a recess was taken from 1:37 p.m. to 1:43 p.m.)

THE WITNESS: So on page 19 of my TVT-O report.

BY MS. FITZPATRICK:

Q. Okay.

A. One of my references was Footnote 42, and this

particular footnote was out of that technical file -- excuse me, design history file, so I don't know if you want the estimate number or how --

Q. Sure, estimation number is fine.

A. Okay.

Q. Is that what you have in front of you?

A. Yes.

Q. Okay.

A. That's Number 42.

Q. Okay.

A. Just give me one more second here.

(Discussion off the record.)

A. I can tell you out loud. I was just trying to explain the report.

So on page 19, the other footnote of interest is Number 41. That is a broader reference all-inclusive to the design history file, including, it says the design controls, risk analysis, and that is referencing different procedures.

Now, 42 specifically, is the TVT-O, DSA, not -- not called an FMEA, but it was a risk analysis, and on page 20 of my report, I have an excerpt directly from that risk analysis.

BY MS. FITZPATRICK:

Q. And so is it -- so I've got your testimony correct, what you note in Footnote 42 of your report, which is the document I have in my hand now, this is the document that you believe has independently looked at the risks posed by the trocars used by the TVT-O device as opposed to the risks posed by the trocars used with the TVT-R device?

A. That is my understanding as I read it, and that's what's described in the scope that I have on page 20.

Q. Okay. So anything that I would be looking for and that you would be relying on for your opinion that the trocars were independently assessed is going to be in this document that starts with ETH.MESH00259416; correct?

MR. DAVIS: Object to the form.

A. That's partly correct, partly not correct. The part that's correct is this is the DDSA, but at other times in the design history file, there are many references to the design verification and validation, and those were associated with mitigation of risks. So indirectly, they are incorporated in the risk analysis.

BY MS. FITZPATRICK:

Q. Okay. Now, taking a look at what you have on page 20 of your report.

A. Okay.
Q. And I think that references this DDSA.
A. Yes.
Q. Which stands for "Device Design Safety Assessment"; correct?
A. Yes.
Q. The DDSA that was done by Ethicon prior to the launch of the TVT-O, you'll agree with me it was done on the components of the device as opposed to the -- all of the components put together in a single device; correct?
MR. DAVIS: Object to the form.
A. May I look at that, please?
BY MS. FITZPATRICK:
Q. Sure. I'm just looking right on page 20 where you have, "Scope of the design safety assessment. Define the scope of this risk assessment." It says, "This risk assessment was completed on (check one): Device, subsystem or component."
A. That's what they checked, but --
Q. Okay. Ethicon may have been wrong when they said that. Go ahead and take a look.
A. No, the scope marked on components there, it's my understanding that this document asked questions that were broader than just single components. That's a part

of the DDSA. They have a checklist. The beginning questions are systems-related, and then when they reviewed it further, they incorporated more detail about the components.

Q. Okay.

A. That were specific to the components.

Q. But you'll agree with me that Ethicon, at least itself, considered that DDSA to be based on the components and not the device itself?

MR. DAVIS: Object to the form.

A. I believe that -- excuse me, sorry.

I believe that their perception was, and why they put components, was because the components were changing.

BY MS. FITZPATRICK:

Q. Okay. Did they perform a risk assessment on the entire device itself or did the risk assessment consist of looking at the components individually?

MR. DAVIS: Object to the form.

A. There's several revisions here and I just want to refresh myself a second.

As I tried to explain, the scope was because of the different components, but the qualitative and quantitative characteristics worksheet incorporates

questions that are system-related. For example, they speak in terms of sterilization. That would be a system level.

BY MS. FITZPATRICK:

Q. This case isn't about sterilization; is it?

MR. DAVIS: Object to the form.

A. Actually, what would be important is if, for example, the new components couldn't be sterilized in the same way as the TVT, that would have a big bearing on the potential for new risk associated with the new kit.

BY MS. FITZPATRICK:

Q. Do you -- is it your understanding that these lawsuits are about the inability to sterilize components of the TVT-O device?

A. Ma'am, I need to qualify that if there was a difference in sterilization that affected the sterilization of the entire system, the team would have to consider that, and that, certainly, would have impact on the mesh had they had to change the sterilization. So I would think that evaluating the question of sterilization as a system is very germane to their work in risk analysis.

Q. Okay. I don't want to be here late, so I want to just focus on --

A. I know, but I'm trying to explain why.

Q. I want to focus us on, though, on the stuff that I think is relevant to the lawsuit, so let me ask you the question again.

Do you believe that this lawsuit has anything at all to do with the inability to sterilize the TVT-O system? Is that your understanding from talking to Ethicon's lawyers, that that has anything to do with this case?

MR. DAVIS: Object to the form.

A. I can't answer the question the way you've asked it because it -- in my due diligence and review of the documentation, regardless of what the attorneys would have spoken to me about, I had to consider whether or not when they did the change to the TVT-O, did they consider the impact on the system, including packaging and sterilization and all of the components. I would -- I would have to consider all of that as -- when I'm reading the risk analysis, did they consider that question; and yes, they did, because that could have impacted the properties of the mesh if they had had to change the sterilization cycle.

BY MS. FITZPATRICK:

Q. Okay. What else besides sterilization and

packaging do you see as germane to a system-wide analysis of the risk posed by TVT-O devices when it's permanently implanted into women?

A. Well, another one is human factors. One of the most critical issues in the TVT-O was the difference in the surgical procedure, so if -- and as I understand, the TVT-O was desirable to reduce risks associated with the surgery of the standard TVT-R, particularly the bladder puncture, and so as these folks were looking at the use-related hazard worksheet, that is clearly a system-level review of the entire TVT-O product.

So they were compelled to do a revised risk assessment because of the changes to the component; thus, the check box, and then when they review the DDSA and go through the DDSA procedure, they're compelled to review all of these checks, and all of these checks are at a system level as well as component level.

Q. Okay. So you believe that Ethicon performed both a system risk assessment and a component risk assessment when introducing the TVT-O to the market?

A. Yes.

Q. Is that fair?

A. That's fair.

Q. Okay. And that -- you're getting that

information from the document that you've identified in Footnote 42 of your report?

A. And 41.

Q. Oh.

A. Because 41 included the mitigation activities, the physician consulting. In fact, it even included the pre-review of the risk associated with the TVT in general.

Q. Okay.

A. So the whole design history file, which we did not bring, is associated with mitigating risk.

Q. Okay. And one of the ways, you'll agree with me, that a company can mitigate risk is by providing warnings to physicians and patients concerning the risks inherent to a particular device; correct?

A. That's generally correct, yes.

Q. Okay. And so, Ethicon had an obligation to warn, through its IFU, physicians of the risks that are inherent in the TVT-R device; correct?

MR. DAVIS: Object to the form.

A. Generally stating, yes.

BY MS. FITZPATRICK:

Q. Okay. And they had an obligation to warn the physicians through the IFU about the risks that are inherent in the TVT-O device; correct?

MR. DAVIS: Object to the form.

A. It's hard to --

BY MS. FITZPATRICK:

Q. Just general. I mean, that's a general principle?

A. Like love of mother and apple pie.

Q. It's difficult to disagree?

A. Right, right.

Q. And you'd agree with me that the IFU has to incorporate in it the risks that are inherent in the specific product. So the IFU for the TVT-R should include warnings about the risks that are inherent to the TVT-R; correct?

MR. DAVIS: Object to the form.

A. I guess you're going with, "And thus, the TVT-O." I can't answer this question the way you have posed it.

BY MS. FITZPATRICK:

Q. Sure. Well, let me ask you to break it down.

There's an IFU for the TVT-R; correct?

A. Yes.

Q. And that's what a physician who's using the TVT-R can consult; correct?

A. Yes; that's correct.

Q. There's a separate IFU for the TVT-O; correct?
A. Yes.
Q. And that contains information for a physician to look at who's using the TVT-O; correct?
A. Correct.
Q. And you would agree with me that the TVT-O IFU should include the warnings about risks specific to the TVT-O; correct?
MR. DAVIS: Object to the form.
A. If there are any specific ones --
BY MS. FITZPATRICK:
Q. Correct.
A. -- to the TVT-O that are different.
Since TVT-R came first, if there were new changes, if the changes introduced new risks that rise to the level of warning --
Q. Okay.
A. -- then they should be on the labeling decks.
Q. Okay.
A. That's mother and apple pie, yes.
Q. So if there's a difference in the risk profile, assuming there's a difference in the risk profile for the TVT-R versus the TVT-O, that should be reflected in the instructions for use for each of those products;

correct?

MR. DAVIS: Object to the form.

A. Mother and apple pie, generally speaking, yes.

BY MS. FITZPATRICK:

Q. Okay. Are you aware that the FDA recently proposed to reclassify the trocars that are used with the TVT-R and the TVT-O from Class 1 to Class 2 medical devices?

MR. DAVIS: Object to the form.

A. I haven't been following that. No, I didn't appreciate that.

BY MS. FITZPATRICK:

Q. Let me go ahead and get this marked as Exhibit 16, and I'm going to give you the full copy. In the interest of time, to keep us -- I'm going to give you the couple pages that I'm using, but you have access to the full document if you want to take a look.

A. I probably won't be coming back to this, then. I can get this off my desk?

Q. No, don't get rid of that yet because you reminded me there's something I didn't follow up on.

A. Okay. I just want to close it so I don't get distracted. Okay.

(Whereupon, Exhibit 16 was marked.)

A. This is this (pointing)?

BY MS. FITZPATRICK:

Q. Yes. What I have here is I just copied the couple pages I'm going to use to save us some time from having to shuffle through the big thing.

A. Oh.

Q. But if you want the big one, it's in front of you for reference.

A. Thank you.

Q. So what I've handed you is a document that's entitled "Reclassification of Urogynecological Surgical Mesh Instrumentation" from the Food & Drug Administration, the Executive Summary dated February 26, 2016.

And that's about a month ago; correct?

A. Yes.

Q. And you, before being here today, you weren't aware that this had happened; correct?

A. I hadn't been following this, no.

Q. And no one from Ethicon told you there was a potential reclassification of the trocars from a Class 1 to Class 2; correct?

A. I hadn't been notified, no.

Q. Okay. So what -- if you can take a quick look

at a couple of issues. The FDA, looking at -- I don't think I've got page 4 here. I think you've got page 4 on the bigger one, and I apologize. Was looking -- if you look at page 4 of the bigger one, I'm sorry, that's the only -- I don't have this copied right.

It states that, "The FDA believes that intraoperative --" I'm sorry, I want to make sure you're on the same page, it's about halfway down -- that "The FDA believes that intra-operative and peri-operative adverse events such as organ injury and perforation, hemorrhage and bleeding and nerve injury and pain can be reasonably attributed to the urogynecological surgical mesh instrumentation and not the surgical mesh."

Do you see that?

MR. DAVIS: Where are you reading from? I don't think she sees it.

A. I don't exactly see it.

BY MS. FITZPATRICK:

Q. I'm sorry, I should have had this page. I have it on page 4, but since I can't find it right now, I'll find it at a break and I'll come back to that question. But let me go on in page 5.

And so what the FDA is looking at here is at the bottom, what you'll see is that the FDA identified --

"The FDA identified a total of 463 MDRs using particular search criteria."

Do you see that right at the bottom here on page 5?

A. 483, okay.

Q. Yeah. 438.

A. I mean 438.

Q. A total of 438 of the MDRs were submitted by manufacturers; 14 by a user facility, and 11 were voluntary.

So I want to take a look on page 7 -- well, page 6 to 7, there's a Table 2 that summarizes the MDRs by manufacturer.

Do you know what an MDR is?

A. Yes.

Q. Okay. And can you tell me what an MDR is?

A. Medical device reports.

Q. And those are reports that are made of adverse events or complications that are experienced with a particular medical device; correct?

A. Sort of correct; medical device, serious injuries that are device-related.

Q. Okay.

A. And deaths.

Q. Okay. And those are required to be reported to the FDA; correct?

A. Yes, ma'am.

Q. Okay. And if you look at Table 2, it summarizes the MDRs related to the surgical -- the trocars by manufacturer, and if you look at page 7, it indicates that there were 90 reports, MDRs, submitted concerning the Ethicon trocars; is that right?

MR. DAVIS: Object to the form.

A. It's what is reported by FDA on page 7.

BY MS. FITZPATRICK:

Q. Okay. Correct. And you don't have any independent verification of these numbers, but I'm correct in what I'm reading here from the FDA?

A. From the FDA.

MR. DAVIS: Object to the form.

BY MS. FITZPATRICK:

Q. And do you have any reason to believe that the FDA is misrepresenting or mischaracterizing the MDRs that it has received concerning the Ethicon products?

MR. DAVIS: Object to the form.

A. Ma'am, "misrepresentation" could be an incorrect term. In my judgment, they could be listing in this table, not a misrepresentation, but a categorical

representation, which doesn't necessarily mean that they always get the categories right.

BY MS. FITZPATRICK:

Q. Okay.

A. I'll just give them that benefit of the doubt.

Q. Okay. Now, Boston Scientific Corporation, which is on the previous page, Boston Scientific has a higher MDR count than Ethicon; correct, just by sheer numbers?

A. According to the FDA.

Q. And I'm not asking you to endorse or adopt these numbers as correct or incorrect.

A. All right.

Q. But we'll just agree that, at least, this is what's reported here.

A. That's what it says.

Q. Okay. And the vast majority of the Boston Scientific MDRs are associated with the Pinnacle Pelvic Floor Repair Kit and the Uphold Vaginal Support System.

Do you see that?

A. That's what it says, yes.

Q. Now, is it your understanding that the Boston Scientific Pinnacle and Uphold devices do not use a trocar in the same way that the Ethicon products do?

A. No, ma'am. I have no understanding of the Boston Scientific products.

Q. Have you ever heard of the Capio device?

A. No, ma'am.

Q. Okay. So you just don't know?

A. I do not -- do not know.

Q. Okay. Now, let me set that aside for a minute and let me mark this next one as Exhibit 17. And, again, I've copied a few pages that I'm actually going to look at, but I'm going to give you the full document for you to take a look at if you'd like.

(Whereupon, Exhibit 17 was marked.)

BY MS. FITZPATRICK:

Q. And so, what you're looking at is a PowerPoint presentation that's entitled, "Reclassification of Urogynecological Surgical Mesh Instrumentation" from the FDA on February 26, 2016.

A. Yes, ma'am.

Q. Okay. And if you look at the short one, just help us because it's hard to find these pages.

A. Okay.

Q. Now, the FDA did a review of published literature in support of its proposed reclassification; correct?

A. That's what they say, yeah.

MR. DAVIS: Object to the form.

BY MS. FITZPATRICK:

Q. And you'll agree with me that a review of published literature is something that a medical device manufacturer should do with respect to its own particular medical devices; correct?

A. It's a requirement as a part of the MDRs.

Q. Okay. And so Ethicon here has an obligation to monitor the medical literature and to educate itself on what is being reported about its pelvic organ prolapse and SUI products in the medical literature; correct?

MR. DAVIS: Object to the form.

A. It's my understanding as a part of the MDR process, most companies do do that, yes.

BY MS. FITZPATRICK:

Q. Okay. And so here, the FDA states that it conducted a review of the published literature. If you can turn to page 31, it's got a PowerPoint slide that outlines the methods that it used. If you could quickly read through that and ask me -- and let me ask you if you believe that the methods that the FDA sets forth on this slide are reasonable for a -- to conduct a review of published literature.

A. No, I can't say that this would be sufficient information for me to know how well they did their job.

Q. Okay. Just so these methods --

A. It doesn't --

Q. I'm not asking you whether they did it right or they didn't do it right.

Do these methods that are set forth, do those look reasonable to you as an expert here as reasonable methods for conducting a review of published literature?

A. As I say, I don't have any key words to go by here. This is a broad generalization of, I'm sure, what their methods were, so I can't evaluate this slide.

Q. Okay. So you can't say, one way or the other, whether these --

A. It's not enough information provided here.

Q. Okay. Fair enough. If you turn to page 32. Let me ask you, you've got a lot of experience with the FDA; right?

A. I have some.

Q. Okay. And it's part of -- a significant part of the job that you've done for the past however many years; correct?

A. Yes.

Q. Do you have any reason to believe that the FDA

would do an improper review of published literature when they're looking at the reclassification of a surgical device?

MR. DAVIS: Object to the form.

A. Would they do an improper?

BY MS. FITZPATRICK:

Q. Uh-huh (affirmative).

A. I believe they could do an insufficient -- incorrect, yes. Yes.

Q. Okay. How often do you think that the FDA does an insufficient or an --

A. I couldn't give you a number, but I've had experience where the key word searching and the methodology has not been as precise as it should be.

Q. Okay. Do you think Ethicon does a better job at their literature reviews than the FDA does?

MR. DAVIS: Object to the form.

A. I can't say that they do a better job, but I can give you an example of how they've done their job, and I think you'd see it's quite different from what's represented here by FDA.

BY MS. FITZPATRICK:

Q. Okay. So you think that Ethicon does a more thorough review of the medical literature than the FDA?

A. Probably searching published literature is all in the key words, and not only the included words, but the way you exclude certain terms, and without looking at their methodology, I can't compare it to the Ethicon methods.

Q. Okay. I was asking you more generally, but we don't -- and I don't want to spend your time on this.

Taking a look at the bottom of page 31, it indicates that the FDA found 207 references that the FDA deemed to be relevant for its inquiry on this reclassification question; correct?

A. Yes.

Q. And if you look at the page 32, what the FDA has done here is it's divided up those 207 references into whether it's -- the reference refers to an SUI or a POP?

A. Yes.

Q. And then, whether it's a retropubic transobturator or mini-sling procedure for the SUI; correct?

A. Yes.

Q. And then, whether it's a transvaginal repair or an abdominal repair for the POP; correct?

A. Yes.

Q. Okay. And set forth those references.

Now, turning to page 33 here.

A. Excuse me.

Q. Sure.

A. May I just say something?

Q. You can say anything you want.

A. I think that these 207 that we're speaking of are broke down on 32, but I haven't actually confirmed that.

Q. Okay.

A. I mean, I'll take it at their face value.

Q. Fair enough. And on page 33, what the FDA does is it indicates that it extracted data from those 207 studies for three major categories of adverse events; organ perforation and injury, second is vascular injury and bleeding, and third is nerve injury and pain.

Do you see that?

A. Yes.

Q. And this is specifically associated with the trocars?

A. Yes.

Q. Now, turning to page 34, the first thing that the FDA noted is -- or looked at is organ perforation and injury, and I want to focus here on the retropubic and the transobturator; okay?

A. Yes.

Q. And it found that the rate of organ perforation and injury associated with the retropubic trocar ranged between 0.3 percent to 23.8 percent; correct?

MR. DAVIS: Object to the form.

A. That's what they've written, yes.

BY MS. FITZPATRICK:

Q. And for the transobturator, they found that it ranged from 0.2 percent to 5.8 percent; correct?

MR. DAVIS: Object to the form.

A. That's what they've written.

BY MS. FITZPATRICK:

Q. That's what they've written.

And I'm not asking you to endorse these numbers, but assuming that these numbers are correct, you'll agree with me that there is a difference in the risk profile between the retropubic trocar and the transobturator trocar relative to organ perforation and injury; correct?

MR. DAVIS: Object to the form.

A. No, ma'am, I can't say correct because --

BY MS. FITZPATRICK:

Q. Tell me why.

A. Because we're talking about a literature search that went all the way back to 1997, and considering the time involved and how these particular numbers are laid out here, I would expect the retropubic to be higher because it's an older product and it goes back to '97, and in this circumstance of this table, I -- I can't make out any useful information other than this is how they broke their numbers down.

Q. Okay.

A. I mean, it's math. If you agree with the math, but I don't know, looking at this, anything more than that. So I -- I don't feel qualified to give you any information here about this chart.

Q. What does "rate" mean to you?

A. It's a percentage, but what I'm saying is I don't know if this is with respect to time. I mean, we could have -- when a new product comes out, you could have a big burst and then they taper off, and FDA's not provided any kind of temporal characterization of these numbers. So this is -- you know, you could take it for what it's worth, but I don't have enough information to make any judgment on this chart.

Q. Okay. Does it raise questions, at least, as to whether there's a difference in the rates between organ

perforation and injury for retropubic and transobturator?

A. It raises question --

MR. DAVIS: Wait. Object to the form.

A. Sorry. It raises questions in my mind how these numbers were derived, and I just saw this for the first time today, and I don't have any opinion about this document (pointing) or FDA's numbers. I can tell you whether or not I think they did the math right, but I can't give you any opinion about this document.

BY MS. FITZPATRICK:

Q. Well, sure you can. Let me ask you a hypothetical question.

Assuming -- and we're going to assume, I'm not asking you to endorse the FDA numbers but assuming that the FDA numbers are right, if there's a risk of organ perforation and injury from 0.2 to 5.8 percent with the retropubic procedure and a risk of organ perforation and injury from a retropubic procedure that goes from 0.3 to 23.8 percent, assuming that those are correct numbers, you would agree with me that there is a difference in the risk profile between the retropubic trocar and the transobturator trocar when it comes to organ perforation and injury; correct?

MR. DAVIS: Object to the form and asked

and answered. Go ahead.

A. I will state that I cannot -- cannot confirm your statement. I do not agree with your statement. There's not enough information here to agree with your statement or disagree with your statement because these numbers are not reflecting the -- anything about the learning curve, the time reference.

BY MS. FITZPATRICK:

Q. Okay.

A. All these -- all these folks did was they went to 1997 and grabbed up a bag of articles from the literature, went through and counted numbers, then they divided those numbers into categories. And when you see a number that ranges from .3 to 23.8, in my world, that should immediately cause me to wonder how did you get that big a swing of numbers, and so I would need to look at the 54 versus 74 papers that they're getting those numbers out of. I couldn't give you any information about this chart.

Q. Okay. Fair enough.

Did Ethicon, in any of the documents -- and you've got a lot of binders around this room and you've got a lot of documents you looked at -- have you seen anything where Ethicon attempted to do what the FDA has done in this document?

MR. DAVIS: Object to the form.

A. I don't know what FDA attempted to do in this document, but I have certainly seen clinical evaluation reports where Ethicon has reviewed literature over a certain period of time, they've stated in their document how they did their literature searches, and they've reported the incidences that they found in the literature.

And so, I believe on a par with looking at the clinical experiences that Ethicon has, persistently through the years, monitored the literature, and thus, the complication rates reported in that literature.

BY MS. FITZPATRICK:

Q. Do you believe that Ethicon has an obligation to be monitoring the medical literature to see if there's a difference in their risk profile for the retropubic trocar versus the transobturator trocar? Is that something Ethicon should be doing?

MR. DAVIS: Object to the form.

A. I don't know what you mean by "risk profile," but I believe that Ethicon does that and should be doing it, yes.

BY MS. FITZPATRICK:

Q. Okay. And so you -- you believe that somewhere in all of the documents you have -- and I can

look at from your report -- I will find in there a place where Ethicon has looked specifically at whether there's a difference between the risk of organ perforation and injury from the retropubic trocar versus the risk of organ perforation and injury from the transobturator trocar?

MR. DAVIS: Object to the form.

A. Specifically, I can tell you there is a report comparing the -- well, I should say complications and complaints, evaluated differently between the two systems, and I can't recall if they broke it down to instrumentation.

BY MS. FITZPATRICK:

Q. Okay. And knowing that you haven't looked at this report, let me just ask you a general question on page 35.

Do you agree with me that Ethicon should be looking at whether there's a difference in the risk profile between the TVT-R trocar and the TVT-O trocar for vascular injury and bleeding associated with those devices?

MR. DAVIS: Object to the form.

A. I can't say from recall if that was conducted, but I can say that that would be a reasonable thing to be doing.

BY MS. FITZPATRICK:

Q. Okay. And would it also be reasonable to expect Ethicon to be looking at the relative risk profile of nerve injury and pain caused by the TVT-R trocar versus the TVT-O trocar?

MR. DAVIS: Object to the form.

A. If their information is broken out that -- in that detail, it would be reasonable. I believe that I can recall a document that did that.

BY MS. FITZPATRICK:

Q. Okay. And you would agree with me that if Ethicon concluded that there was a difference, a significantly higher risk of a complication from the TVT-R device versus the TVT-O device, that information should be reflected in the instructions for use that are given to physicians; correct?

MR. DAVIS: Object to the form.

A. I can't say that that would be true. No, I don't know that.

BY MS. FITZPATRICK:

Q. Okay. Well, let me ask you this.

A. May I clarify?

Q. Well, let me clarify that -- maybe that will help -- maybe that will help.

MR. DAVIS: If you need to explain your answer -- if you need to explain your answer.

THE WITNESS: I just want to explain the answer there.

MR. DAVIS: You're entitled.

BY MS. FITZPATRICK:

Q. Sure, go ahead.

A. When -- when we're looking at differences sometimes and whether or not that difference needs to get to the literature, you have to also appreciate the differences in practices and preferences. So if you were just to take a number and say, "Well, this number is higher and that number is lower," that doesn't necessarily compel you to go out and say, "This week, it was higher and the other one was lower." You don't react in that way just because you find some anomalies in numbers for a while, particularly when a new product is being introduced. So that's what I wanted to clarify.

Q. Okay. But just to clarify for right now, the TVT-O's been on the market for a long time. It's not a new product that was just introduced; correct?

A. It's not new.

Q. Okay. Let me mark this as Exhibit 18.

(Whereupon, Exhibit 18 was marked.)

BY MS. FITZPATRICK:

Q. Ms. Duncan, do you know what a meta-analysis is?

A. Yes.

Q. Okay. And what I've put in front of you is a meta-analysis that was done by a Dr. Megan Schimpf and published in 2013 concerning sling surgeries for stress incontinence in women.

A. Okay.

Q. And I'm going to represent to you that this article is one that your gynecology experts for Ethicon have relied on for their opinions concerning both the TVT-R and TVT-O device in this case; okay?

And what I want you to do is I want you to turn to Table 4, which is on page 71.E11; okay? And about halfway down Table 4, there's a section entitled, "Retropubic vs. Obturator Midurethral Slings."

Do you see that?

A. Yes.

Q. And what they say here is, "For women considering retropubic or transobturator midurethral sling, we recommend either intervention for objective or subjective cure."

And that means how well it cures the SUI;

correct, or corrects the condition?

MR. DAVIS: Object to the form.

A. I would have to read more, but if you say so.

BY MS. FITZPATRICK:

Q. Okay. "And that decision be based on which adverse events are of greatest concern to the patient."

Do you see that?

A. I see that.

Q. And then underneath, it says, "Retropubic slings result in lower rates of sling erosion, need to return to operating room for treatment of sling erosion, groin-like pain and vaginal perforation."

Do you see that?

A. I see that.

Q. And underneath, it says, "Transobturator midurethral slings result in shorter operative time, fewer bladder urethral perforations, less perioperative pain, fewer urinary tract infections and less overactive bladder symptoms."

Do you see that?

A. Yes, I see that.

Q. Now, you will agree with me that, according to this Table 4, Dr. Schimpf is indicating that there's a different risk profile for the retropubic slings versus

the transobturator slings; correct?

MR. DAVIS: Object to the form.

A. The context is within this paper and the metadata analysis they did. I can't agree with that declarative statement you just made. Within the context of the paper and the metadata that she's looking at, obviously, this is the conclusion she's made.

BY MS. FITZPATRICK:

Q. Okay.

A. I don't know for a fact how that would be reflected in other practice.

Q. Well, let me ask you it differently.

If Ethicon's experts, urogynecological and gynecological and neurology experts, the medical experts, have testified that this paper does, indeed, indicate that there are different risk profiles for the retropubic and the transobturator midurethral slings, you would have no reason to disagree with those expert opinions; would you?

MR. DAVIS: Object to the form.

A. This is outside my field of expertise.

BY MS. FITZPATRICK:

Q. So you would have no reason to disagree with those. You would defer to those -- maybe a better way, you would defer to Ethicon's clinical experts on the

different clinical --

A. It's outside my expertise.

MR. DAVIS: Let her finish her question.

THE WITNESS: Sorry.

BY MS. FITZPATRICK:

Q. Do you defer to the Ethicon clinical experts on the clinical differences in the risk profiles of the retropubic versus transobturator slings?

A. Yes, I do.

Q. Okay. Now, what does Ethicon consider to be a Legacy product?

A. It is my recall that the term "Legacy product" with respect to the documents that I was looking at, I don't know if they use it in a different terminology elsewhere, but within the context of these topics, it means the products that were introduced to the marketplace prior to the issuance, adoption to use your word, of ISO 14971.

Q. Okay. And there are a series of risk assessments that were done on those Legacy products; correct?

A. There have been a number, yes.

Q. Okay. And you know that the Legacy products include the TVT-R and the TVT-O; correct?

A. Say it again, I'm sorry.

Q. That the Legacy product risk assessments include the -- apply to the TVT-R and to the TVT-O; correct?

A. They characterize them as Legacy products, yes.

Q. Okay. And those risk assessments for the Legacy products that you're talking about don't differentiate between whether those products are mechanically-cut or laser-cut; do they?

A. It's my recall they do not.

Q. And they don't differentiate between whether it's a retropubic approach or a transobturator approach; correct?

A. I can't recall if they broke those out or not.

Q. And those Legacy product documents create a risk profile for the whole family of the Legacy document -- the Legacy products out there, collectively, as opposed to individually breaking those out; correct?

MR. DAVIS: Object to the form.

A. I'm not clear on your term "risk profile." Can you tell me what you mean by that? It's not a term I use.

BY MS. FITZPATRICK:

Q. I should be using the term "risk assessment," not risk profile.

So the risk assessments in the Legacy products that we're talking about create a single risk assessment for the TVT-R mechanically-cut, the TVT-R laser-cut, the TVT-O mechanically-cut, the TVT-O laser-cut. They create a risk assessment for those -- all of those products together; correct?

A. Ethicon's Legacy Risk Report combined those products, yes.

Q. Okay.

MR. DAVIS: Can we stop just one second? I just want to know how much time we've been on the record?

THE REPORTER: We have -- in 14 minutes, we'll be at four hours.

MR. DAVIS: Okay.

MS. FITZPATRICK: I'm not even going to get to 14 minutes.

MR. DAVIS: Okay. I just didn't know if you had any follow-up after I ask questions. That's fine, go ahead.

BY MS. FITZPATRICK:

Q. In looking at the -- you've reviewed the IFUs

for the TVT-R and TVT-O?

A. Yes.

Q. Have you ever compared the warnings, precautions, contraindications, adverse events that are set forth in the TVT-R versus the TVT-O IFU?

A. I did not do that.

Q. Okay. So you don't know whether those warnings, contraindications, adverse events, whatever Ethicon calls them, are the same for both products or different for those products; do you?

A. I did the report separately, so I don't -- I did not compare. That was not a part of it.

Q. Okay.

MS. FITZPATRICK: Can you give us one minute?

MR. DAVIS: Sure. We'll be right out here.

(Whereupon, a recess was taken from 2:31 p.m. to 2:37 p.m.)

MR. DAVIS: Did you have something you wanted to --

MS. FITZPATRICK: Well, let me end and you can make it part of -- part of your questioning. I don't have any further questions for you at this time.

THE WITNESS: Okay.

EXAMINATION

BY MR. DAVIS:

Q. Ms. Duncan, did I hear you say you had something you wanted to say?

A. Yes. During the bathroom break, it occurred to me I had misspoken of inside-out and outside-in, so I want to clarify that. The obturator approach is inside-out, and the other was outside-in, so instead of outside in.

So the outside in -- I'm not sure which way I had it. Outside in, the original TVT-R had the potential for the bladder perforation. So the design for the new obturator approach is going inside-out, and I don't know if I had that right or not when I spoke, but then I got to thinking maybe I hadn't. But the outside in was the original TVR and it had the higher observed bladder perforation at the time when they were doing the risk assessment. That's my clarification, okay.

MR. DAVIS: Can I proceed?

MS. FITZPATRICK: Yeah.

BY MR. DAVIS:

Q. I just have several questions.

Ms. Duncan, when you were asked questions

today, I know a number of the questions you were asked, counsel opposite would use the word "safe" in the question.

A. Yes.

Q. And you would, then, answer the question.

A. Yes.

Q. In answering those questions where they were using the word "safe," what definition were you applying in your mind for the word "safe"?

A. The safety of the product certainly has to be considered in the context of the alternative therapies, and the unknown risks associated with the product, that's -- when I think of safe, I'm thinking there's no unexpected risks and the alternatives would have comparable risk or worse. So if I'm making a safer product, I would be safer than the alternative surgical procedure or methods that would be available to me.

Q. And you've mentioned ISO 14971. In answering those questions, were you applying a different definition of safe than what appears in ISO 14971?

A. No, I think that's comparable to 14971.

Q. And then, another question, series of questions that you were asked about, if Ethicon knew about certain risks, should they be in the IFU.

Do you recall, generally, some of those questions?

A. Yes.

Q. And I wrote down one of your answers. You said, "Risks that rise to the level of warning."

Can you explain what you meant by that?

A. In the FDA and the European standards, we talk in terms of -- we see them talk in terms of precautions, cautions and warnings. So a precaution is an effort I would need to do in advance because failure to do so may cause a harm, and a caution says I could have a harm if certain factors combine together, and then a warning is at a level where it is known that certain conditions can -- can create a harm if you fail to take certain precautions. So a warning is more of a certainty than a -- than a harm that only might occur under certain conditions.

Q. And you were asked about whether you could base your -- or whether you had to have FDA standards in your report in order to justify your opinions in your report.

Do you recall, generally, those questions?

A. Yes.

Q. And can you -- can you explain to the Court to what extent, if any, you based your report on Ethicon's --

Ethicon's own internal procedures?

A. Ethicon, at a certain point in their own history, began to incorporate, based on jurisdictions, certain international standards as well as U.S. guidance documents. So the procedures at the troop level governed the activity of the troops.

So when Ethicon converts standards and practices into their procedures, those are the activities that the specific employees are expected to employ. Ethicon does not expect that, on an ad hoc basis, people just go and grab guidances and the like to do their job; they want them to follow standardized procedures, which have incorporated the currently-adopted guidances and standards on a global level wherever Ethicon practices their sales.

Q. Okay. And if the Court decides that the Court does not want to hear any testimony or any opinions based on FDA standards, does that present any problem for you to present your opinions?

A. No, I would be referring to the Ethicon procedures and had Ethicon implemented their own internal procedures for these various obligated activities, but keep in mind that, even practicing 14971 for risk assessment, it's incumbent upon us to understand the rules

of the land that we're operating in. So if I go to Canada, I have to do my risk analysis in the context of any specific Canadian regulations, and if I go to Saudi Arabia, then I do my risk assessments incorporating those.

And so, when you have an international worldwide company, their procedures have to reduce those unique regulatory requirements and standard adoptions into their procedures on an ongoing basis. That's why you see revision after revision after revision, because different standards are adopted in different jurisdictions at different times.

Q. That's all I got.

REEXAMINATION

BY MR. WALLACE:

Q. You were just asked by Mr. Davis about whether or not you could speak to the -- well, let me ask it a different way.

You were asked whether or not certain regulations, whether or not you could testify with or without those regulations, including FDA regulations.

Do you recall what he just asked you about that?

A. I recall it.

Q. And what I think I heard, and you tell me if I'm wrong, is you said it wouldn't change my analysis of their internal standards because those changed over time in response to different standards that were adopted around the world.

That's what you said; right?

A. Yes.

Q. Now, coming back to that, you also said that, if I understand you correctly -- and again, tell me if I'm wrong -- that you really have to put your opinions in the context of the regulatory environment in which those entities operate; right?

MR. DAVIS: Object to the form.

A. When I did my assessment, I had to appreciate where the work was being done, where the product was being sold and the time that it was being sold.

BY MR. WALLACE:

Q. Okay. So let's take the United States, for example.

As I understand what you're saying, you cannot offer your opinions without considering how the FDA regulations would apply to Ethicon in the United States; right?

A. I can offer the opinions and exclude different

countries, if that's what the job is, but now you're -- the request that was given of me was to assess the scope of design control and review, risk management and how the various companies of Ethicon implemented those activities.

Q. Okay. But to answer my question, though, I'm specifically talking about the United States and this product being sold in the United States; okay?

So with that in mind, forgetting about other countries for a moment, can you tell us, as you sit here, whether or not your opinions would be the same if the FDA regulations were removed from your analysis?

A. Yes, they would be the same.

Q. Why is that?

A. Because I was looking at the documentation of the three products for the evidence of compliance with their internal standards, as well as other obligations.

Q. Okay. So that's what I'm getting at.

You can say your opinion would be, then, slightly revised to say, "I can tell you that they complied with their internal standards;" right?

MR. DAVIS: Object to the form.

BY MR. WALLACE:

Q. But when we're referencing external standards, you wouldn't be able to give that portion of your opinion?

MR. DAVIS: Object to the form.

A. I would still be able to give that. I think that's what I did. I'm not following -- I mean, if I looked at the procedures, I also looked at the standards that were in place at the time, and not only the standards, but with respect to time. So which standards were in effect in which location with respect to time.

BY MR. WALLACE:

Q. Okay. We're talking about the United States, though. Keep that in mind.

A. Okay.

Q. Just for this line of questioning.

You're able -- your opinions would change in the sense that you can talk about whether or not Ethicon followed its own internal standards in the U.S. and if the FDA piece was removed from your analysis, if I hear you correctly, what you're saying is, "I, then, wouldn't be talking about external standards as it relates to this product's performance in the United States."

MR. DAVIS: Object to the form, and asked and answered.

A. That's not a correct statement, as I understood you to say it. That's very difficult to understand.

I've said before that a job was what I referred to as due diligence, looking back at the records, how they complied with procedures and the procedures that were enforced with respect to regulations and standards in the jurisdictions with respect to time, and I can certainly eliminate the question of how did they deal with Canada or how did they deal with U.S. or how did they deal with Saudi Arabia and still make an expert opinion on their diligence with respect to design control and review and risk management.

BY MR. WALLACE:

Q. Okay. So what standards would apply in the U.S. if you removed the FDA analysis that you've done in your reports?

A. What standard would apply in the U.S.?

Q. What external standards would apply in the U.S.?

A. I think -- I can give you one example; ISO 10993.

Q. Okay. What else?

A. I think, to some extent, the ISO 14971 would still apply.

Q. You agree with Ms. Wilson in that context if that's her testimony?

A. I can't hear you very well.

Q. You would agree with Ms. Wilson, if that was her testimony, that that standard would apply?

MR. DAVIS: Object to the form.

A. Not with respect to time. You can't -- I mean, you're asking me in a very general way, but I have to bring you back to that all of this work had to be done with respect to the time in which it was done. No single product stayed still.

BY MR. WALLACE:

Q. What -- what other standards would apply?

A. Depending on the time frame you're talking about, it may or may not have been EN 1441, depending on the location you're speaking of --

Q. U.S.

A. -- it may have been an EN standard.

If you make a product in the U.S. and you sell it to another country, you have to abide by those country rules you're selling it into, so --

Q. Again, my questions are limited right now for selling to women in the United States.

A. All right.

Q. That's what -- these women that you -- you realize that you've been designated to testify with

respect to women that have brought claims in U.S. courts; correct?

A. Yes.

Q. And under the U.S. legal system?

A. Yes, sir.

Q. And you've offered opinions on that; right?

A. Broadly speaking, all of the standards.

Q. So my question remains:

Tell me what other standards that would apply in the United States that would apply to these women that have brought these claims against Ethicon.

A. Sterilization standards, packaging standards. There's a host of standards that all the medical device companies, regardless of their location, attempt to satisfy for various reasons. Maybe it's because of regulatory, but maybe because of an understanding of the state of the art.

Q. Are there any standards that are not listed in your report that you want to tell us about today that might apply?

A. I can't answer that. I don't -- I don't know. Now you're asking me something that was not specific -- I mean, I wasn't asked to look at a -- list in my report all of the applicable standards. That was not the scope of

the report. I could go do that.

Q. Let me ask you a question that would, perhaps, short-circuit your concern that you weren't asked to do certain things.

Are all the standards that would apply to your opinions listed in your reports?

A. I'll say the vast majority. I can't say that they're all listed individually, and if you will allow me, that is because some of these standards existed by different names in different locations. Even ANSI, AAMI, ISO will sometimes even change the name of a standard when they adopt it, so you're asking a very broad question that needs a very specific answer.

THE REPORTER: AAMI?

THE WITNESS: A-A-M-I.

MR. WALLACE: I'm done.

REEXAMINATION

BY MR. DAVIS:

Q. I have a follow-up on what you just said.

Ms. Duncan, you brought with you, I noticed, various Ethicon's internal procedures.

Have I placed before you the book on PR602-003?

A. Yes.

Q. And can you look -- is it -- do you have a recollection as to whether Ethicon, itself, in its procedure, would list -- did it have a practice of listing references to the various standards that they're applying in developing their own procedures?

A. They did, yes.

Q. And do they list ISO, for example, ISO 13485 as one of the standards that they have opted to choose in their own PR602-003 as a basis for compliance?

A. That was an example in 1996, and then they also referenced ISO 9001, which is not even a medical standard, and a Canadian standard that is listed here, and that's what I was trying to describe; that on any given time we have a procedure, we have to look at the scope of references in the back that were being considered when they were writing the procedure, and this list may change.

Q. And as I recall, I understand that, in your report, you explained that the FDA has not, itself, adopted ISO 13485?

A. That's correct.

Q. Or when I say "adopted," I mean recognize it as a consensus?

A. That's right.

Q. But since Ethicon listed, in development of

its own procedures, did you consider the extent to which Ethicon's files on these various products met the requirements for 1345?

A. I certainly did, and I even went and got copies of those older standards to look at them.

Q. And so, if the Federal Court does not allow testimony and opinions concerning compliance with FDA standards, have your opinions addressed Ethicon's compliance with ISO 13485 with respect to these products?

A. Certainly.

Q. And what about ISO 14971?

A. To the extent that it was applicable at the time that Ethicon was doing their work, yes.

Q. That's all I have.

MS. FITZPATRICK: Nothing further.

MR. DAVIS: Read and sign.

MR. WALLACE: We'd like it expedited. Need it Monday.

(The deposition of Elaine Duncan concluded at approximately 2:58 p.m.)

* * * * *

CERTIFICATE

I, Barbara J. Carey, a Registered Professional Reporter and Notary Public for Anoka County, Minnesota hereby certify that I reported the Deposition of Elaine Duncan, on the 31st day of March, 2016, in Minneapolis, Minnesota, and that the witness was by me first duly sworn to tell the whole truth;

That the testimony was transcribed under my direction and is a true record of the testimony of the witness;

That I am not a relative or employee or attorney or counsel of any of the parties or a relative or employee of such attorney or counsel;

That I am not financially interested in the action and have no contract with the parties, attorneys, or persons with an interest in the action that affects or has a substantial tendency to affect my impartiality;

That the right to read and sign the deposition by the witness was not waived;

IN WITNESS WHEREOF, I have hereunto set my hand this 4th day of April, 2016.

_____

Barbara J. Carey
Registered Professional Reporter
Notary Public

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

Elaine Duncan DATE

Subscribed and sworn to before me this

_____ day of _____, 20____.

My commission expires:_____

_____

Notary Public